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Food and Drug Administration

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CERTAIN FLUOROCARBON (CHLOROFLUOROCARBON) PROPELLANTS IN SELF-PRESSURIZED CONTAINERS

Warning Statement Requirement

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

[Docket No. 76N-0459]

CERTAIN FLUOROCARBON (CHLOROFLUOROCARBON) PROPELLANTS IN SELF-PRESSURIZED CONTAINERS

Warning Statement Requirement

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This final rule requires a package label warning statement on foods, over-the-counter (OTC) human drugs, animal food, animal drugs, cosmetics, and nonrestricted medical devices in self-pressurized containers propelled by certain fluorocarbons, specifically, fully halogenated chlorofluoroalkanes (chlorofluorocarbons). This warning is established to alert the consumer that chlorofluorocarbons may harm the public health and environment by reducing stratospheric ozone. This warning will not be required on products specified in the regulation in which the use of a chlorofluorocarbon propellant is essential.

EFFECTIVE DATE: All finished products initially introduced into interstate commerce on or after October 31, 1977 shall comply with this regulation.

FOR FURTHER INFORMATION CONTACT:

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RELATED ACTIONS: 1. The Consumer Product Safety Commission (hereafter referred to as the "Safety Commission") has published elsewhere in this issue of the FEDERAL REGISTER a proposed rule to require a warning, similar to the one established by this rule, on all products containing chlorofluorocarbon propellants that are subject to the Consumer Product Safety Act (15 U.S.C. 2051 et seq.) (CPSA) (Ref. 18).

2. The Food and Drug Administration (FDA) will publish shortly in the FEDERAL REGISTER a proposed rule that would prohibit the use of chlorofluorocarbon propellants in all products subject to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 201 et seq.) (FFDCA), except for specified essential uses. In the same issue of the FEDERAL REGISTER, the Environmental Protection Agency (EPA) will propose a rule that would restrict nonessential propellant uses of chlorofluorocarbons under the Toxic Substance Control Act (15 U.S.C. 2601 et seq.) (TSCA).

SUPPLEMENTARY INFORMATION: The warning established by this rule was proposed in the FEDERAL REGISTER of November 26, 1976 (41 FR 52071). In a notice of intent published in that same issue of the FEDERAL REGISTER (41 FR 52070), the Commissioner stated his intention to phase out nonessential uses of at least chlorofluorocarbons in products subject to the FFDCA. No change has been made in the text of the warning as proposed, but minor revisions have been made in the final regulation. Under these revisions, propellant uses of chlorofluorocarbons are subjected to the regulation, animal food is expressly subject to the regulation, the form of the animal drug regulation is changed, the minimum type size requirement of 1/16 inch is applicable to all products subject to the regulation, and additional drug and device products have been determined to be essential and are exempted from the regulation. The reasons for the changes are discussed below.

APPLICABILITY OF REGULATION

The final regulation contains a provision limiting the applicability of the regulation to the use of chlorofluorocarbons in whole or in part as a propellant to expel other liquid or solid contents under pressure. The propellant uses of chlorofluorocarbons are the easiest uses to judge in terms of essentiality because the use involves simply a means of product delivery. Alternative product delivery systems for almost all products have long existed. The propellant uses are also by far the major uses of chlorofluorocarbons in FDA-regulated products. The nonpropellant uses of chlorofluorocarbons involve various functions, and more analyses of the alternatives are necessary before restricting these uses.

Better Federal coordination is promoted by limiting regulatory action at this time to propellant uses of chlorofluorocarbons. At this time, EPA intends to restrict only propellant uses of chlorofluorocarbons; around June 1978, EPA intends to issue a proposal relating to nonpropellant uses (Ref. 19). FDA has coordinated, and will continue to coordinate, its regulatory action with regard to chlorofluorocarbons with the other Federal agencies having regulatory responsibilities. Accordingly, FDA will proceed with a proposal to prohibit nonessential nonpropellant uses of chlorofluorocarbons after appropriate consultation with other agencies.

The Food and Drug Administration's definition of "propellant" in the final rule and in the phaseout proposal is similar to the definition of "aerosol propellant" that EPA plans to use in its proposed rule. Under the definition, a chlorofluorocarbon is not considered a propellant if the pressurized container contains only chlorofluorocarbons or only gases.

Because only propellant uses are being regulated at this time, the warning and proposed phaseout will not apply to pressurized cylinders of chlorofluorocarbons and ethylene oxide used for sterilization purposes, or to cylinders used simply to transport chlorofluorocarbons for industrial uses, as in the case of cylinders transporting liquid food freezant. Also not covered by the present action are FDA-regulated products containing only chlorofluorocarbons in which the chlorofluorocarbon is the active ingredient.

The warning and proposed phaseout are also not applicable to the use of chlorofluorocarbons as a stabilizer in food toppings and spreads, even though the chlorofluorocarbon has an incidental propellant effect. The data submitted in response to the notice of intent indicate that in these products the chlorofluorocarbon is used in small amounts, usually less than 1 percent of the product, to stabilize the food after dispensing and to prevent waste. The phaseout of this will be considered with the nonpropellant uses.

Generally, the warning is applicable whenever a chlorofluorocarbon is used in whole or in part as a propellant, even though the chlorofluorocarbon has another function, or the product contains another propellant or has a barrier pack to prevent release of the propellant during use. A chlorofluorocarbon propellant could be considered to serve several functions in many instances simply because of its general characteristics, e.g., as a fire retardant, or coolant. If the existence of a dual function generally exempted products from the regulations, the scope would be reduced and the purpose of reducing nonessential product delivery uses would be diluted. Accordingly, the regulation is expressly applicable whenever a chlorofluorocarbon is used in whole or in part as a propellant. The only exceptions are stated in the regulation and, as already discussed, in these products the chlorofluorocarbon has a distinct nonpropellant purpose not generally found in products. These uses of chlorofluorocarbons will be phased out, if not found to be essential, when action is taken later with respect to all the nonpropellant uses of chlorofluorocarbons.

The final regulation is also revised to delete the term "volatile." Chlorofluorocarbon propellants are or become gases after release and pose similar risks of ozone depletion. As used in the proposal, the term "volatile" was intended to be simply descriptive and not to limit the scope of the regulation. Thus, the deletion of this term should have no effect.

COMMENTS ON PROPOSAL

One hundred and sixty-two comments were received in response to the proposal to require the warning established by this rule. One hundred and thirty-three comments endorsed the Commissioner's decision to initiate regulatory action to phase out chlorofluorocarbons, with 79 of these comments expressly endorsing the requirement for a warning. Fifteen comments opposed the initiation of any regulatory action, 13 of which expressed opposition to the warning requirement. Fourteen comments were concerned with exceptions for specific categories of products, or with alternative products, and expressed no clear views for or against regulatory action. The Commissioner's discussion of the comments received and his response to them are set forth below.

All comments received within a week of the close of the comment period have been analyzed and counted with the timely comments. Some comments were

received even later. The final procedural regulations governing FDA rulemaking procedures have only recently been published (see the FEDERAL REGISTER of January 25, 1977 (42 FR 4680) and subsequent recodification published in the FEDERAL REGISTER of March 22, 1977 (42 FR 15553)), and the Commissioner has exercised some leniency in accepting late comments. The comments received more than a week late have been screened, and none presented any new matter significantly different from the issues raised in the timely comments. Their numbers have not been calculated, however, in the description below of the comments received.

To give a comprehensive and orderly discussion of the scientific issues, all the comments raising scientific questions are discussed below irrespective of whether they were submitted in response to the proposal to require the warning (Docket No. 76N-0459) or in response to the notice of intent (Docket No. 76N-0460). Furthermore, the Commissioner has discussed some late comments raising scientific issues because of his continuing efforts to monitor new scientific developments. Similarly, to permit an orderly discussion, all comments relating to the essentiality of products subject to the warning requirement are discussed below irrespective of the docket to which the responses were submitted.

Because the proposed warning was the first step in the overall regulatory action being taken, the Commissioner included in the docket for the warning proposal all comments that related to the general need for regulatory action as well as those that bore the designated docket number. A few comments submitted specifically in response to the notice of intent discussed issues that bore on the warning proposal. The Commissioner recognizes that some persons may have been confused about the proper docket to which they should have submitted their comments. Accordingly, the Commissioner has reviewed the comments in the docket for the notice of intent and, if a comment was timely and dealt expressly with the proposed warning, he has discussed the comment below to the extent pertinent to the warning. Some comments included in the docket for the warning requirement raised issues that related solely to the intended phaseout, and these issues will be discussed in the preamble to the proposed phaseout.

LEGAL ISSUES: STATUTORY AUTHORITY

1. Three comments asserted that the Commissioner lacked statutory authority to require the proposed warning either for cosmetics or for all products. One of the comments argued that section 201(n) of the FFDCA (21 U.S.C. 321(n)) does not authorize the Commissioner to require affirmative disclosures in cosmetic labeling, and that it allows the Commissioner to take account of material omissions in labeling only in the case of express claims made in the labeling. The comments also argued that the Commissioner could require warnings under section 201(n) of the FFDCA only with respect to a "serious hazard" and risks to the immediate user of the product under customary conditions of use, but not risks to the health of other persons who may be indirectly injured as a result of the use of the product. All three comments protested that the Commissioner does not have any authority, either under the FFDCA or under the National Environmental Policy Act (NEPA), to regulate environmental damage caused by products subject to the FFDCA. Another comment stated that FDA has statutory authority, comparable to that of EPA and the Safety Commission, to regulate environmental and health risks posed by products within FDA's jurisdiction.

The Commissioner rejects the comments that he lacks statutory authority to issue this regulation. The Commissioner has relied for the warning requirement not only on section 201(n) of the FFDCA but also on the adulteration and misbranding provisions of the FFDCA, and on NEPA, and has discussed in the preamble to the proposed rule the basis for reliance on these provisions. He agrees that the FFDCA authorizes warnings and affirmative disclosures only with respect to serious hazards but, as more fully described below, unlike the comments, the Commissioner believes that the hazard to which this warning is directed is a serious one. Every product subject to the FFDCA, including a cosmetic, makes an implied claim of safety. Accordingly, section 201(n) of the FFDCA requires an affirmative disclosure of any serious hazard the product poses. The Commissioner has previously explained (see the FEDERAL REGISTER of March 3, 1975 (40 FR 8912)) his basis for believing that section 201(n) of the FFDCA requires affirmative disclosures about safety risks.

The health risks against which the act is directed are not limited solely to risks to the immediate user. Some sections of the FFDCA, such as section 601(c), expressly refer to risks that may render the product "injurious to health," a phrase that Congress used in the same sense as the term "injurious to users" found in other provisions such as section 601(a). This indicates that Congress used both terms in a broad sense reflecting a general concern for all health risks found in products subject to the FFDCA. Risks to the health of the immediate user under the intended conditions of use are most frequently the focus of regulatory concern. The FFDCA provides authority, however, to protect the public against other risks. The Commissioner has, for example, required warnings about the risk of death from intentional misuse of products, and risks of explosion from improper storage or disposal of self-pressurized containers, a risk which affects other persons besides the intended user, e.g., 21 CFR 101.17 (formerly 1.13 prior to recodification published in the FEDERAL REGISTER of March 15, 1977 (42 FR 14302)), 369.21, and 740.11. The Commissioner's authority to issue those regulations has been upheld in an initial challenge (*Cosmetic, Toiletry and Fragrance Assn* v. *Schmidt*, 400 Supp. 57 (D.D.C. 1976), appeal pending). The failure to warn householders of substantial risks of injury or illness, such as flammability risks, posed by foods, drugs, and cosmetics may make the product misbranded (16 CFR 1500.81).

The usual condition of use of self-pressurized containers involves a release of chlorofluorocarbons into the atmosphere. Thus, the risks from chlorofluorocarbon release is a hazard associated with customary use of the products.

Recent congressional action reflects a recognition that FDA has authority to regulate unreasonable risks to health or the environment which are directly or indirectly caused by foods, food additives, drugs, cosmetics, and devices. Congress exempted these products from the recently enacted TSCA. By creating the exemption, Congress did not intend to leave any gaps in the regulatory authority to deal with risks posed by chemicals. As stated by the House Committee, in H. Rept. 94-1341, 94th Cong., 2d Sess., page 10 (1976): "The intent of the committee in excluding these items is to exclude from coverage under the bill items which may be regulated under the Federal Food, Drug, and Cosmetic Act. By adopting the definitions given the items by the Act the Committee has made the exclusion of these items from the bill coextensive with the authority to regulate them under the Federal Food, Drug, and Cosmetic Act." In view of Congress' concern with preventing unreasonable direct and indirect health and environmental risks posed by chemicals, Congress would not have created the exemption if it did not accept as the appropriate interpretation of the FFDCA that FDA can regulate these risks when posed by foods, food additives, drugs, cosmetics, and devices.

Furthermore, industry representatives have argued that the States do not have authority to require warnings about environmental and other risks posed by products containing chlorofluorocarbons, in part, because State authority is preempted by FDA's statutory authority to require cautionary labeling. One trade association brought to the attention of a State agency FDA's notice in the FEDERAL REGISTER of July 16, 1975 (40 FR 29914), relating to ozone depletion risks from fluorocarbons, with the comment that "It is clear that the Federal Government not only has jurisdiction over aerosol products, but also is actively exercising that jurisdiction * * * " (Ref. 20). The preemption argument is premised on the existence of statutory authority in FDA to require cautionary labeling with respect to all types of risks posed by products subject to the FFDCA. Thus, at least until FDA initiated this action, many segments of the affected industry have apparently accepted that FDA's authority reaches the risks from ozone depletion posed by the use of chlorofluorocarbons in products subject to the FFDCA.

LEGAL ISSUES: NEED FOR UNIFORM FEDERAL APPROACH

2. One comment contended that the warning was discriminatory, and therefore illegal under the Administrative Procedure Act (5 U.S.C. 706(2)(A)), because FDA did not have a "uniform approach" for regulating the aerosol products under its jurisdiction that was "consistent" with the approach of the other Federal agencies regulating aerosol products containing chlorofluorocarbons. According to the comment, EPA has been asked by FDA and the Safety Commission to be the lead agency in developing a uniform regulatory approach, and EPA has considerable experience and expertise in environmental matters. Therefore, FDA should withdraw the proposed warning and coordinate its actions with EPA in phasing out uses of chlorofluorocarbons. The comment further stated that FDA's proposed warning was inconsistent with the statement required by EPA on pesticides, and that FDA's proposal was developed "apparently" without consultation with EPA. It was also argued that Congress endorsed a postponement of any proposals for regulatory action until January 1978, as evidence by the provisions authorizing EPA to issue regulations in 1978 governing substances that affect the stratosphere, as found in bills to amend the Clean Air Act that passed each House in the last session of Congress. Other comments also criticized FDA for acting differently from EPA, but did not assert that FDA action was illegal simply because it was different from EPA's approach.

The Commissioner believes that coordination among Federal agencies is appropriate and has pursued coordination actively on this matter. Already in the record, as reference 17, is a letter from the then Commissioner to the Council on Environmental Quality (hereafter referred to as "the Council") in which the then Commissioner stated his intention to initiate a phaseout of the use of chlorofluorocarbons in products subject to the FFDCA. He suggested that the Council coordinate Federal regulatory activity through the Interagency Task Force on Inadvertent Modification of the Stratosphere (IMOS Task Force) and that the Council designate EPA as lead agency to coordinate the environmental impact statement. As a result, the Council held meetings with the affected Federal regulatory agencies (Ref. 21). All the agencies agreed to cooperate in preparing the necessary documents relating to the environmental impact of the action being taken, with EPA taking the lead in coordinating the preparation of these documents. EPA has coordinated this effort through the working group responsible for developing the EPA phaseout proposal. FDA personnel have participated in the meetings of the working group which is chaired by EPA. The working group has also served to keep each agency informed of the steps of the other agencies in preparing for the phaseout.

A commitment to coordination, however, does not mean that all agencies will act identically, or that any one agency has the lead responsibility to determine the approach that should be taken by all. The aim of coordination is to explore the possibilities of taking similar action, and to understand the reasons for a different approach if one agency believes it advisable. The Commissioner rejects the argument that the approach of FDA is illegal merely because it is not identical with the approach adopted by another agency. Each agency has the responsibility for administering a distinct statute, and its actions apply to different types of industries and uses. Thus, the particular regulatory situation an agency deals with may warrant different treatment. In addition, judgments may differ on matters of policy. Each agency has the ultimate responsibility to be sure that it has acted appropriately under its particular act.

The Environmental Protection Agency and FDA plan to propose essentially parallel and complementary phaseout actions. The proposals differ in matters of form, but that difference is largely attributable to the differences in terminology and structure of the statutes and existing regulations each administers. The Safety Commission has preliminary found that the use of certain chlorofluorocarbon propellants present an unreasonable risk of injury and has instructed its staff to prepare a draft notice proposing to declare products subject to the CPSA containing the propellants to be banned hazardous products (Ref. 22). The Safety Commission also stated that if EPA proposes a rule under TSCA which renders action by the Safety Commission unnecessary the Safety Commission may terminate its proceeding.

The Federal agencies have differed to some extent in their approach to a labeling requirement about the presence of chlorofluorocarbon propellants. All three agencies have recognized the suitability of imposing some type of labeling requirement, but they have differed in their approach to the text and the applicability of the requirement, in part because of reasons of policy, and in part because of differences in the type of products they regulate.

The Safety Commission has published elsewhere in this issue of the FEDERAL REGISTER a proposed rule that would require a warning on all the aerosol products containing chlorofluorocarbons it regulates. The text of the warning proposed by the Safety Commission will be similar to the one required by FDA in this regulation.

The Environmental Protection Agency has also required labeling but only in the form of a descriptive statement on pesticides that "This product contains chlorofluorocarbon 11 (or 12)." EPA has not required a warning on pesticides, or any labeling on any other products it regulates. The Food and Drug Administration informed the Council, EPA, and the Safety Commission in early October that FDA intended to propose a warning statement as the first step in a phaseout program. The Environmental Protection Agency subsequently issued its notice providing for labeling on pesticides but not a warning. The Food and Drug Administration considered the text of the EPA labeling notice before it issued its proposed regulation; FDA decided that a warning requirement was more appropriate. In the Commissioner's judgment, consumers may not understand the significance of a presence of a chlorofluorocarbon in a product, and the hazard posed, from a statement that simply states that the product contains a chlorofluorocarbon. Some consumers may assume the statement is made to indicate an especially valuable ingredient, and they may interpret the statement as a reason for purchasing the product. Thus, on policy grounds, FDA adheres to the view that a warning statement should be required.

The Environmental Protection Agency has made only pesticides subject to its labeling requirement. Many of the other uses of chlorofluorocarbons regulated by EPA are industrial ones, and labeling on the immediate container of industrial products may have less impact on purchases.

The Commissioner also points out that most nonessential uses of chlorofluorocarbon propellants occur in products subject to FDA's jurisdiction. Eighty percent of the releases of chlorofluorocarbons from self-pressurized containers in the U.S. has been from FDA-regulated products. Thus, the Commissioner believes he has a special responsibility to ensure that action is taken promptly to reduce the risk from these nonessential uses under FDA's jurisdiction. The establishment of the warning requirement, provided for in this document, helps to meet that responsibility.

The Commissioner rejects the argument that FDA should not act because of the timetable for regulatory action found in unenacted bills to amend the Clean Air Act in the last session of Congress. The bills were not enacted and, like all bills, they are not the authoritative expression of congressional intent. Furthermore, the bill reported by the Conference would have allowed EPA to act before 1978 if the Administrator found that regulation was necessary to prevent an effect that might reasonably have been anticipated to endanger the public health or welfare (Ref. 23). Furthermore, the bills did not repeal FDA's existing authority, and the Conference Report indicates that there was no intention to supersede or preempt the authority other Federal agencies might have with respect to the same or similar hazards presented by products within their jurisdiction.

LEGAL ISSUES: INSUFFICIENT BENEFIT AND NEED FOR ENVIRONMENTAL IMPACT STATEMENT

3. Three comments stated that the Commissioner's warning proposal was irrational because it provided too speculative and small a benefit, even under FDA's estimates, to justify the requirement or to warrant the cost of relabel-

ing. Furthermore, the comments argued that the warning would have even less effect on ozone reduction and on health than assumed by FDA. Alternatively, the comments argued, if the proposed warning would have sufficient impact to be justified, any final regulation mandating a warning would be unlawful under NEPA and FDA's environmental regulations in 21 CFR Part 25 (formerly 21 CFR Part 6, prior to recodification published in the FEDERAL REGISTER of March 22, 1977 (42 FR 15553)) unless accompanied by a comprehensive final environmental impact statement.

The Commissioner has discussed below in more detail the reasons why some comments did not view the warning as having a sufficient benefit to be rational. He concludes that, notwithstanding the continued uncertainty about the precise degree of ozone depletion, and the exact extent of adverse health and environmental consequences that may occur, the risk of harm is substantial and is sufficient to warrant taking regulatory action at this time to reduce nonessential uses of chlorofluorocarbons. The requirement is a rational first step in the program to reduce and phase out nonessential uses of chlorofluorocarbons. It can be implemented relatively quickly, and it should discourage nonessential users temporarily. While the warning is in effect, FDA can proceed with the consideration of a phaseout action based upon a comprehensive consideration of the full environmental and inflation impact of a phaseout, coordination of the action with other Federal agencies, and examination of any new information or research developed in this period.

Several comments stated that the remarks of the Commissioner in the preamble to the proposed regulation, referring to the limited and temporary nature of the warning, revealed that the Commissioner recognized that the warning would have no appreciable benefit. The comments misconstrued the Commissioner's views. The Commissioner believes the warning is beneficial and useful as an interim measure. The warning should reduce use of chlorofluorocarbons to some extent, facilitate informed consumer choice, and promote a reasonable transition to a phaseout of nonessential uses.

The remarks of the Commissioner quoted in the comments were made to explain why a separate environmental impact statement need not be prepared for the warning requirement. Important though the warning is, in comparison with the proposed phaseout, the impact of the warning is not significant. The warning will have less effect because it is temporary and it will not ban manufacture or use of any products. It is not possible to know the extent to which the warning itself will reduce use. The effect of the warning, whatever its degree, will be subsumed within the overall regulatory action being taken. This warning is the initial step of the total phaseout action. The environmental effect of the overall action has been evaluated comprehensively in connection with the phaseout of nonessential propellant uses of chlorofluorocarbons in FDA-regulated products which FDA will propose shortly. The draft environmental impact statement relating to the phaseout will be publicly available within a short period. Thus, the Commissioner continues to believe that a separate environmental impact statement for the warning need not be prepared and completed before a final rule requiring a warning is issued.

At the meetings held by the Council to coordinate Federal agency action with respect to fluorocarbons (Ref. 21), FDA described its intent to require a warning as an initial step, propose a phaseout later, and prepare an environmental impact statement only for the phaseout. The Council representatives concurred in the position that a separate environmental impact statement is not necessary for the warning requirement.

The Commissioner notes that he has prepared an environmental impact analysis report and an environmental assessment report on the effects of a warning. The warning is being required for environmental and health reasons. The preamble to the proposed rule discusses the reasons in detail, and this document responds to the comments received from the public on the preamble. Thus, in substance, the Commissioner has already stated the environmental impacts of a warning and the public has had an opportunity to comment. If anyone believes that the overall phaseout action, or the warning which is a part of that action, has an adverse environmental effect that has not been considered, they may comment on the phaseout proposal and the draft environmental impact statement. The Commissioner will monitor comments received, and will act promptly if the comments indicate the need for any changes.

Lastly, the Commissioner points out the time period during which the warning is to be in effect is uncertain. In response to comments, as discussed below, he has extended the effective date for including the warning in the labeling. In the phaseout proposal, he has established the tentative target dates for the phaseout. These dates may be extended, however, in response to comments or to achieve suitable coordination with EPA's actions to phaseout nonessential aerosol propellant uses. Thus, the warning could be in effect for less than 2 years, but it is also possible that the duration of the warning could be longer. The Commissioner views the warning as rational, notwithstanding its temporary duration, because the warning can be implemented promptly and can continue until the phaseout regulation becomes effective.

SCIENCE-RELATED COMMENTS

ESTIMATES OF OZONE DEPLETION AND NEED FOR FURTHER RESEARCH

4. Five comments were received regarding the uncertainties in the predictions of stratospheric ozone depletion resulting from chlorofluorocarbon releases. Some of the comments characterized the risks of ozone depletion and adverse consequences from chlorofluorocarbon release as a "speculative possibility" because of the remaining scientific uncertainties. The comments urged that any regulatory action be delayed at least 2 years, until research was completed to explore the scientific uncertainties. All the comments referred to the report (Ref. 8) on "Halocarbons: Environmental Effects of Chlorofluoromethane Release"[1] of the Committee on Impacts of Stratospheric Change of the National Academy of Sciences (NAS Committee) and criticized the Commissioner for not following the NAS Committee's recommendation that regulatory action be delayed for up to 2 years to permit further research. The uncertainties mentioned in these comments included photochemical reaction coefficients and atmospheric transport rates, the nature and amount of "minor species" in the atmosphere, the processes which may control their abundance, the limitations in the representation of atmospheric dynamics by one-dimensional models, speculation about other possible sources of ozone, discovery of new "sinks," such as hydrochlorofluorocarbon 21, which might lower ozone depletion levels, and the existence of chemical and feedback processes not included in the NAS model. One comment submitted late listed several research projects sponsored by an industry association to resolve uncertainties.

The Commissioner is aware that there are uncertainties, but he stated in the preamble to the proposed rule the reasons why he believed action was warranted at this time despite the existence of some uncertainties and the recommendation for further research by the NAS Committee. The best available information still indicates that chlorofluorocarbon release will affect stratospheric ozone to some extent. The principal uncertainty relates simply to the amount of ozone that will be depleted. The NAS Committee found in its report that selective regulation of chlorofluorocarbon 11 and 12 is "almost certain" to be necessary. The Commissioner believes, based on his continued monitoring of the scientific research, that the NAS estimate of ultimate reduction of stratospheric ozone on the order of 7 percent still has general support among the scientific community as the best estimate based on currently available information.

Further research as recommended by the NAS Committee might serve to establish that the ozone depletion level is around 2 percent. The NAS Committee believed that the consequences of a 2 percent reduction are tolerable, but the Commissioner disagrees, as already

[1] The NAS Committee report and the companion report of the NAS Panel on Atmospheric Chemistry, "Halocarbons: Effects on Stratospheric Ozone" (Ref. 9) have recently been published by NAS and are on sale through the National Academy of Sciences, Printing and Publication Office, 2101 Constitution Ave. NW., Washington, DC 20418. The NAS Committee report is $6.25 (Order No. 2529), and the NAS Panel report is $10.25 (Order No. 2532).

stated in the preamble to the proposal. Thus, further research to establish only that the ozone depletion rate is as low as 2 percent would not provide any justification for delaying regulatory action. A delay in protecting the public is not warranted simply to know the precise degree of unjustified risk to which the public might be exposed.

The further research referred to by NAS and in the comments might also uncover inadequacies in the current estimates or explore unidentified factors that might further neutralize the effect of chlorofluorocarbons and even reduce the estimate of ozone depletion significantly below 1 percent. The NAS Committee recommended waiting for further knowledge to reduce these uncertainties, but it recommended against waiting longer than 2 years before making a decision to regulate. The NAS Committee chairman has testified that he doubts that the NAS Committee would be uncomfortable with the actions so far proposed by the regulatory agencies (Ref. 24). He also indicated that "(w)ithout the (National Aeronautical and Space Administration (NASA)) program directed to stratospheric research the Committee could not have honestly stated that it expected important gains in knowledge over the next two years" (Ref. 24).

NASA has released a preliminary report updating the scientific assessments about chlorofluorocarbons 11 and 12 which was based on workshops conducted by the Goddard Space Flight Center (Ref. 25). The preliminary report states that there is "little doubt" that ozone in the stratosphere will be destroyed by the release of chlorofluorocarbons 11 and 12 and concludes, on the basis of the known information, that the ultimate ozone reduction will be between "5 and 9 percent" if release continues at 1975 production rates. A final report from NASA is expected to be released in September 1977.

The Commissioner recognizes that there are still uncertainties about the estimates made in the NAS reports and the preliminary NASA report. Some of the areas of uncertainty were specifically addressed in the comments on the proposed rule and have been discussed in more detail below. Ongoing and new research could change the best current estimates of ozone depletion attributable to chlorofluorocarbon emissions. Continued research to resolve the remaining scientific uncertainties is desirable, and the Commissioner will continue to monitor the scientific developments and will consider any comments on these matters submitted in response to the proposed phaseout. As he has already indicated, he will revoke the warning requirement if further research shows it is warranted. But precisely because the research is probing into new areas, it is not possible to predict whether and how the research will change current estimates or how long it would take to confirm whatever initial results the research produces. As stated by one of the scienists for DuPont in congressional testimony, "The major surprises are * * * likely to come in the area of unknown chemistry on which one cannot really speculate. The current government and industry research programs should greatly reduce the possibility of surprises of this kind within the next year or two" (Ref. 26).

The fact remains that the best information currently available indicates that chlorofluorocarbon release poses risks that have unacceptable consequences. In view of the nonessentiality of propellant uses of chlorofluorocarbons, the Commissioner does not believe it warranted to delay a warning requirement to await the results of further research because of the "possibility of surprises" that might change the assessment that chlorofluorocarbons pose an unacceptable risk. As one of the comments supporting the Commissioner's action phrased it, in referring to the requests for time to do further research: "By all means perform your study, but do it in a smaller laboratory. Too many people live in this one."

5. A comment disputed the statements in a letter from F. S. Rowland, cited in the preamble to the proposed warning (Ref. 14), that on the basis of scientific developments, ozone depletion from chlorofluorocarbon release could be estimated as roughly 13 to 16 percent. The comment contained statements criticizing the Commissioner for including the letter, and the higher ozone depletion estimates it contained, as part of the basis for issuing the proposed rule.

The letter was cited as one of several recent developments that suggested that the ozone depletion figures might be even higher than the 7.5-percent figure estimated by NAS. The Commissioner believes it was a relevant report and the citation of it permitted the scientific community and the public to comment on it. However, the comments received indicate that the methods at arriving at higher estimates made in the letter are disputed. Accordingly, the Commissioner is taking this action on the basis that the best current estimate of the amount of ozone depletion that will result from continued chlorofluorocarbon release is a range with a median on the order of 7 percent.

MINOR SPECIES AND POSSIBLE "SINKS" FOR CHLOROFLUOROCARBON

6. Several comments referred to the significant effect chlorine nitrate could have on the calculations of ultimate ozone depletion resulting from emissions of chlorofluorocarbons 11 and 12. The inclusion of chlorine nitrate in some computer models measurably reduces the predicted impact of these chlorofluorocarbons on stratospheric ozone.

The preliminary NASA update (Ref. 25) did not use the pressure dependencies for the rate of formation of chlorine nitrate assumed by the NAS Panel and recommended a rate independent of pressure. While this change taken alone would reduce the NAS ultimate ozone depletion estimate by a factor of 2, it has not significantly altered the overall estimate of the amount of ozone depletion in the preliminary NASA update. Furthermore, Professor Gutowsky, head of the NAS Panel on Atmospheric Chemistry, has stated (Ref. 27) that, as far as he had been able to ascertain, the constants recommended by the NASA staff were not intended to be a "complete, definitive reevaluation of the kinetics data" and that the near-maximum constants used for chlorine-nitrate "are not in accord with some of the experimental data."

7. A comment suggested the possibility of an additional stratospheric sink for chlorine radicals, that of hydroxyl chloride. According to the comment, catalytically active chlorine oxides may react with water in the stratosphere to form hydroxyl chloride which will not react readily with ozone.

The Commissioner notes that even if this intermediate compound were formed, it would be much less effective than chlorine nitrate in preventing ozone destruction for two reasons. First, it would not tie up catalytically active nitrogen oxides in addition to catalytically active chlorine, as chlorine nitrate does. In addition, hydroxyl chloride is likely to be more rapidly photodissociated (Ref. 25). Thus, the hydroxyl chloride sink would not appear likely to have a major impact on estimates of ozone depletion, but any further research on this possibility will be monitored by the Commissioner.

8. Three comments discussed the possibility of tropospheric degradation of chlorofluorocarbon 11 to hydrochlorofluorocarbon 21. This claim was based on two independent measurements in the troposphere at levels approximating 10 parts per trillion (ppt). Based on production figures, DuPont could only account for enough hydrochlorofluorocarbon 21 to give a fraction of a ppt in the troposphere. The hypothesis was advanced that the higher levels might be a result of the breakdown of chlorofluorocarbon 11. If so, this would significantly reduce the tropospheric lifetime of chlorofluorocarbon 11. Should a similar conversion of chlorofluorocarbon 12 to hydrochlorofluorocarbon 22 exist, ozone depletion estimates might be lowered by a factor of 3. The comments noted that Professor Gutowsky (Ref. 27) stated that the detection of hydrochlorofluorocarbon 21 in the atmosphere is "an important finding, the details and implications of which should be checked out promptly and thoroughly."

The Commissioner agrees that further research on this hypothesis would be useful. Until these estimates are confirmed, however, they must be viewed with caution. The high level detected might be a result of instrument contamination, and this possibility is currently being considered by the investigators involved. In fact, one of the researchers recently confirmed that his reported measurements were actually the result of instrumental contamination and that he could find no detectible levels of hydrochlorofluorocarbon 21 in the troposphere (Ref. 28).

9. One comment indicated that the reaction of chlorofluorocarbons with stratospheric ions could represent a possible tropospheric sink. A separate comment

and supporting scientific paper concluded, however, that, "At this point atmospheric ion chemistry does not seem to represent a significant tropospheric sink for any of the halocarbon compounds."

The Commissioner concludes that further study is necessary before ion-molecule reactions are considered to be a significant factor in estimates of ozone depletion resulting from chlorofluorocarbon emissions.

TROPOSPHERIC LIFETIMES

10. An unpublished scientific paper was submitted which indicates that chlorofluorocarbons 13, 113, 114, and 115 (all fully halogenated chlorofluoroalkanes like chlorofluorocarbons 11 and 12) have long tropospheric lifetimes and thus if released into the troposphere would be transported into the stratosphere where they would be photolyzed, releasing catalytically active chlorine, in the manner described for chlorofluorocarbons 11 and 12 (Ref. 29).

This paper supports the Commissioner's view that the release of any fully halogenated chlorofluoroalkane poses a threat to stratospheric ozone similar to those documented for chlorofluorocarbons 11 and 12. Thus, the paper provides additional support for the action being taken in this regulation which is applicable to all chlorofluorocarbons.

11. Several papers were submited reporting data on the reaction rates of chlorofluorocarbons and hydrochlorofluorocarbons with the hydroxyl radical (Ref. 30). The faster this reaction rate the more likely the compound is broken down in the troposphere, thus preventing the transport of chlorine into the stratosphere where it could catalytically destroy ozone.

These papers show that chlorofluorocarbons react least rapidly of all halocarbons tested with hydroxyl radical and thus would pose the greatest risk to stratospheric ozone.

STRATOSPHERIC OZONE AND ULTRAVIOLET RADIATION MEASUREMENTS

12. One comment questioned the theory that chlorofluorocarbons may deplete stratospheric ozone because no decrease in ozone has been measured. According to the comment, numerous records show that global ozone has tended to increase over most of the period since 1950, in the fashion predicted by the known cycles of ozone concentrations, and the record appears ample to reveal any contrary trend of detectable magnitude.

The staff of the National Oceanic and Atmospheric Administration (NOAA) confirms that there has been an upward trend in ozone concentrations in the period from 1962 to 1970 (Ref. 31), but a gradual lowering trend has occurred since 1970. Before 1962, the data are too sparse to make any scientifically sound judgment on trends in ozone concentration. If chlorofluorocarbons have depleted stratospheric ozone at a rate that would ultimately reach 7 percent, the present deviation from natural ozone trends would only be in the order of 1 percent (Ref. 4). NOAA estimates that with today's monitoring limitations, one would have to measure changes of 2 to 3 percent to conclude that global ozone levels had deviated from natural trends (Ref. 31). The limitations on human ability to determine changes in global ozone levels depend less on the sensitivity of the method, since existing methods can detect close to 1 percent deviation, than on the uneven distribution of sampling sites throughout the world. Ozone changes over North America and Europe, where most of the monitoring stations are located, may not be representative of ozone changes over the rest of the world. Therefore, even with data showing no detectable changes in stratospheric ozone today, one could not conclude that predicted reductions in global ozone resulting from past chlorofluorocarbon emissions have not occurred.

13. One comment noted that chlorofluorocarbon release is a current concern, even though it has not yet caused measurable ozone depletion, because a decrease could not be detected until further harm is irreversible. The comment suggested, though, that with better and more numerous tracking stations to monitor ozone depletion levels, small decreases in ozone could be detected in time to keep the maximum ozone decrease to only 2.3 percent if uses are ceased immediately upon detection of the decrease.

As noted above, the difficulties in setting up tracking stations are considerable. Moreover, the Commissioner considers the consequences of ozone depletion at the ultimate rate of 2 percent to be intolerable. The detection and identification of an actual ozone reduction if the ultimate depletion rate were 2 percent would take a considerable number of years and require careful calibrations (Ref. 9 at 15–16). The Commissioner will consider any comments submitted on the proposed phaseout relative to the feasibility of more monitoring stations, but will not delay regulatory action to await further exploration of this possibility.

14. One comment stated that a report from the Smithsonian Institution indicated that there has been no increase in the amount of ultraviolet radiation that is hitting the earth, based on studies over the last 5 years.

A communication from the Radiation Biology Laboratory of the Smithsonian Institution indicates that the comment has misinterpreted the data published by the Smithsonian (Ref. 32). The Smithsonian data measurements were of the total ultraviolet radiation band, i.e., all radiation of a wavelength of less than 400 nanometers. The region affected by fluorocarbons is the band of biologically active ultraviolet radiation (UVB) that lies below 320 nanometers, which constitutes only about 2 percent of the total band. The communication from the Smithsonian Institution explained that since UVB is "so much smaller" than the total ultraviolet radiation band "it would be extremely difficult if not impossible to determine any ozone changes or UVB * * * changes using the larger band."

IMPACT OF WARNING OF NONMELANOMA SKIN CANCER INCIDENCE

15. Two comments stated that FDA should focus greater attention on the overall problem of skin cancer rather than on the small contribution of chlorofluorocarbons to this disease. Furthermore, the comments suggested that changes in lifestyle have made such a great contribution to the increased incidence of skin cancer that the risks from chlorofluorocarbon release are trivial in comparison, or at least that the consequences of a further release during the 2-year period that the warning would be in effect are trivial. The argument was made that moving south could result in similar untraviolet radiation exposures as would a 2-year delay in the cessation of U.S. chlorofluorocarbon releases. Following this line of reasoning, the comments stated, would lead to the absurd suggestion that we should warn people about the hazards of moving south, put warning labels on bathing suits and the like.

The comment is similar to some points raised earlier in a letter to FDA (Ref. 33). The writer urged, in particular, that greater emphasis be put on use of more effective sun-screen agents in sunburn preventatives and similar lotions. FDA responded (Ref. 34) that:

> We agree that the increase in incidence of skin cancer resulting from chlorofluorocarbon releases into the atmosphere will only be a part of the total increase in incidence of such cancers (chlorofluorocarbon releases in 1950 are only now beginning to result in observed cancers). We agree that attempts should be made to prevent all cases of skin cancer (all cancers for that matter). For those adverse health effects associated with natural background exposures to ultraviolet radiation, we advocate good public education and information programs so that people are made aware of these associations and can themselves decide the best method of prevention (avoidance, clothing, sun screens, etc.).

The Commissioner recognizes that changes in lifestyle have contributed significantly to the increased incidence of skin cancer. People should be educated about the accompanying hazards of increased exposure to the sun, but these educational efforts should not be made to appear ridiculous, as in the case of warnings on bathing suits. The Commissioner believes in contrast that the warning on aerosols containing chlorofluorocarbons will be taken seriously by the public, and it may lead to an increased general awareness of the risks from exposure to ultraviolet radiation. It also allows the consumer to make an informed-cost versus benefit choice between, on the one hand, health and environmental risks, and, on the other hand, convenience or other satisfactions from the product.

In any event, changes in lifestyle are difficult to achieve, no matter what educational or other efforts are undertaken. Thus, the risks from increase in ultraviolet radiation should, in the Commis-

sioner's judgment, be assessed in relationship to the existing rates of skin cancer, on the assumption that the preference for light dress in summer weather and increased exposure to sunlight will continue. On that basis, the estimates made in the preamble to the proposed rule about the increased incidence of skin cancer that would result from increased ultraviolet radiation continue to be valid, as discussed further below. Those risks should not be discounted in the expectation that people will change their lifestyle. Furthermore, many people might value the opportunity to be directly in the sunshine more highly than whatever benefits are conveyed by self-pressurized containers with chlorofluorocarbons.

The Commissioner rejects the argument that he should ignore the risks of skin cancer from chlorofluorocarbon emissions because the contribution of other factors to the incidents caused is also large. The incidents that may result from chlorofluorocarbon emissions are significant, and it is within the Commissioner's authority and ability to do something to reduce this part of the risk. Most of the factors contributing to this risk are beyond the Commissioner's regulatory authority. But he has authority to examine the effectiveness of sun screens in sunburn preventatives and other sun preparations. The Commissioner agrees with the point that increased attention needs to be given to effective sun screens. The OTC drug review will examine sunburn lotions and other sun preparations, and the Commissioner intends to weigh the concerns expressed about the effectiveness of sun screens in reviewing these products.

16. One comment questioned the statement in FDA's response to the letter, referred to in the previous comment, that "chlorofluorocarbon releases in 1950 are only now beginning to result in observed cancers."

The statement should have indicated that chlorofluorocarbon releases may result in skin cancer, that no actual cases attributable to this cause have yet been identified, and that, because of the latency period of cancer, cases resulting from chlorofluorocarbon emissions in 1950 are likely to be discernible only beginning now.

17. One comment used DuPont's present best estimate of ozone depletion of 3.7 percent to recalculate FDA's estimate in the preamble to the proposed rule of the number of cases of nonmelanoma skin cancer which might be prevented by imposing a warning label requirement. Use of the DuPont estimate would, of course, lower the number of cases of nonmelanoma skin cancer which would be prevented by imposing a warning label requirement, for it would lower the projected number of cases of skin cancer to be expected.

The Commissioner believes that most current estimates of ozone depletion are still generally around 7 percent rather than the 3.7-percent level estimate by DuPont, which is among the lowest estimates currently being made. Furthermore, the Commissioner regards a 3.7-percent ozone depletion level as posing unacceptable risks. In addition, some recent scientific developments indicate that the original FDA estimate may be conservative.

Based on the report of the IMOS Task Force, the NAS Panel report, and an earlier NAS study (Refs. 4, 9, and 10), FDA used a 1:2 overall amplification rate to calculate the relationship between ozone depletion and the incidence of nonmelanoma skin cancer in making the estimates set forth in the preamble to the proposed rule. A study by Fears (Ref. 35) reports that a 20-percent increase in UVB would result in an increase in cases of nonmelanoma skin cancer from about 35 percent in northern latitudes of the United States, e.g., North Dakota, to about 70 percent in southern latitudes, e.g., Florida. According to these researchers, the relationship between ozone depletion and the increased incidence of nonmelanoma skin cancer is in the order of 1:3.5 to 1:7 in the continental United States. Dr. Alex Green has stated that the approach in the Fears study and in a study conducted by him and his associates gives a biological amplification factor, which is one element in determining the overall amplification factor, that is "substantially greater than the unit factor given in the IMOS report" (Ref. 36).

An overall amplification factor considerably greater than 1:2 has been reported by Rundel and Nachtwey using a model described in Appendix A of the FDA draft environmental impact statement for the proposed phaseout (Ref. 37).

Using the modifications in the skin cancer data reported above, the FDA estimate of numbers of new cases of nonmelanoma skin cancer which might be prevented by not delaying 2 years to initiate regulation and which might be reduced by the warning label requirement would be revised upward, rather than downward as suggested by the comment, by at least a factor of 2. Revised estimates, based on the recent developments, of the number of cases that might be affected by a 2-year delay in regulatory action have been included in the draft environmental impact statement relating to the proposed phaseout. Additional studies to determine more definitely the biological amplification of UVB to incidences of nonmelanoma skin cancer are desirable, and a study of this matter is being initiated by the National Cancer Institute.

18. A related comment suggested that the FDA calculation of the amount of nonmelanoma skin cancer that might occur if regulatory action were delayed was in error because not all of the 300,000 annual cases of nonmelanoma skin cancer are necessarily associated with DUV exposure.

Other factors in addition to solar UVB radiation are known to contribute to nonmelanoma skin cancer, among them ionizing radiation from x-ray sources or radioactive materials, polycyclic aromatic hydrocarbons and chronic irritations and burns. Perhaps 10 to 20 percent of nonmelanoma skin cancer occurs on parts of the body not ordinarily exposed to sunlight, thus indicating that other factors play a role. The extent to which these other factors contribute to nonmelanoma three kinds of evidence—latithese factors appear to be relatively less important than UVB radiation. The NAS Committee has stated that, "For nonmelanoma three kinds of evidence— latitude dependence, body location, and occupational differences—all combine to point closely to the exposure to the sun as a prime cause and to increased incidence as a quite certain consequence of increased [UVB]" (Ref. 8).

IMPACT OF WARNING ON MELANOMA SKIN CANCER INCIDENCE

19. One comment noted that FDA had not made any claim that the incidence of melanoma skin cancer would be affected by the warning label requirement or the proposed phaseout.

Solar ultraviolet radiation may not be as important a contributing factor to melanoma skin cancer as it is for nonmelanoma skin cancer. Melanoma skin cancer occurs with some frequency on parts of the body not exposed to sunlight. Because of these greater uncertainties, FDA did not make an estimate in the preamble to the proposed rule of the number of increased cases of melanoma that might occur if regulatory action is postponed for 2 years. The Commissioner continues to rely on the NAS Committee assessment that malignant melanoma "may well be related to exposures to solar ultraviolet radiation. The relationship which this Committee believes to be likely but yet not completely proven, is not a simple one" (Ref. 8 at 13). A recent report indicates that the incidence of melanoma is increasing (Ref. 38).

NONHUMAN BIOLOGICAL EFFECTS

20. Two comments questioned the potential impact of chlorofluorocarbon releases on plant and animal life. The statement was made that plants and animals are able to tolerate the natural 11-year cycle of variations in the ozone level which are about 7 percent. Another comment urged an immediate ban because of the importance of the ozone layer in protecting the earth from ultraviolet radiation which allows life to form.

The Commissioner notes that NOAA estimates that the variation in the natural 11-year cycle is closer to 5 percent than the 7 percent referred to in the comments (Ref. 31). No data were submitted in the comments to show that these cyclic variations in ozone are not at least in part responsible for well-known cyclic changes, such as those in the distribution of species, reproduction or photosynthesis rates, and migration or behavioral patterns. Thus, perhaps natural fluctuations of ozone do affect plants and animals. Moreover, the existing cyclic variations have resulted in a constant UVB exposure over time. The increase in UVB predicted to result from chlorofluorocarbon emissions would be a

long-term cumulative increase, and it is this kind of exposure which concerns biological scientists. The sensitivity of specific plants and animals to UVB is likely to depend upon many factors, e.g., effectiveness of DNA (Deoxyribonucleic acid) repair mechanisms, avoidance responses, lifespans, and reproductive rates. Plants sensitive to UVB are likely to be the most vulnerable organisms in terrestrial ecosystems because they cannot readily avoid exposure. Depressed rates of photosynthesis and growth are among observed plant responses to high levels of ultraviolet radiation in the vicinity of 300 nanometers (Ref. 39). The broader view of the possible biological impact of cumulative increases of UVB hitting the earth includes the potential impact to ecosystems containing ultraviolet-sensitive plant and/or animal species. Due to the paucity of research in this area, however, UVB effects on ecosystems are uncertain to a considerable degree; the fact remains that, in the judgment of the NAS Committee, the UVB effect on plants and animals are a "strong concern" and a "matter of urgency" for long-term research (Ref. 8). The Commissioner concludes that these risks should be taken into account along with the other risks in judging the need for regulatory action, but they do not warrant an immediate ban without observing the regular procedures for preparing an environmental impact statement and proposing a phaseout.

21. The comment was made that, "Other things equal, there is no plant that cannot be transplanted 150 miles nearer the equator and survive." The comment believed that this indicated a UVB-increase comparable to a move of this distance would have no effect.

Survival of plants is not the only relevant consideration. For example, a reduction in crop yield, particularly agricultural crops, is of considerable significance. The Commissioner concurs with the NAS Committee that additional research is necessary to better understand the effects of UVB on plants and animals.

EFFECTS ON CLIMATE

22. Some comments characterized as merely speculative the possibility that chlorofluorocarbon releases could affect the climate either through ozone depletion or infrared absorption in the troposphere, and they objected to the Commissioner's inclusion of this risk as a basis for the action being taken. The comments also cited Professor Gutowsky's congressional testimony (Ref. 27) that:

> Finally, I am a bit troubled by the inclusion at this time of possible climatic effects of (chlorofluorocarbons) as a reason for their regulation. All environmental changes introduced by man are not necessarily bad * * *.
>
> (A) global warming produced by the greenhouse effect of (chlorofluorocarbons) might extend the growing season further north in Canada and the Soviet Union. Furthermore, the natural trends in global climate span periods ranging from centuries to many thousands of years, and there is some evidence that the natural trend is changing from a warming to a cooling cycle.

Many uncertainties exist about the climate effects. The NAS Committee also recommended further research on these effects as a "matter of urgency" and it recognized that some scientists would emphasize the "possible critical importance of even small effects on climate" and would urge, on this basis, immediate decision to regulate spray can uses. The Commissioner believes the critical importance of climatic effects warrants their being taken into account in assessing regulatory action, notwithstanding the gaps in knowledge about climate. Since regulatory action is justified because of the other risks from chlorofluorocarbons, the Commissioner need not decide now if the climatic risks alone would warrant the initiation of a phaseout or some other type of regulatory action.

The Commissioner rejects the suggestion that chlorofluorocarbon releases should be continued because the releases might have a beneficial climatic effect. We know too little about global weather patterns and long-range climatic cycles at this point to attempt to alter climate and weather on this scale deliberately.

23. One comment said that there was no inherent time delay between chlorofluorocarbon emissions and resulting climate changes. The comment asserted that no climatic changes had occurred recently which could be attributable to chlorofluorocarbons and that any alterations in climate which might occur could rapidly be reversed by decreasing chlorofluorocarbon release at the time such changes were observed.

The basic premise of this comment appears to be incorrect, since the magnitude of the possible climatic effects from chlorofluorocarbon emissions is not known, and since the NAS Committee report indicates that there could be a considerable delay between chlorofluorocarbon release and the cessation of whatever climatic effects it caused. The report stated that if chlorofluorocarbons 11 and 12 releases were to continue at a constant rate, "the amount of direct climatic effect would also flatten out, approaching a steady state, again reaching half of this value in about 50 years. The increase of infrared absorption and emission would similarly reach half of this ultimate value in about 50 years. Resulting climatic effects might be further delayed because of slowness in response in the climatic mechanism" (Ref. 8).

24. Some comments noted that volcanic emissions and other sources of intermittent releases of chlorine have not resulted in climatic alterations.

Again, it must be emphasized that it is the gradual long-term accumulations of chlorine in the troposphere and stratosphere, rather than natural cyclic or intermittent events resulting in ozone reduction, which pose the greatest threats to man directly and through impacts on plants, animals, and climate.

OTHER SCIENCE-RELATED COMMENTS

25. A comment mentioned the formation of chlorine ions in the ionosphere, a region of the atmosphere above the stratosphere, which could affect electron concentrations at this high altitude and lead to changes in global high frequency communication links, since high frequency radio waves are absorbed by electrons in the ionosphere.

This observation indicates that chlorofluorocarbon release could have additional undesirable consequences, but at present this possibility is only speculative. Certainly, further research on the matter would be desirable.

26. One comment questioned the theory underlying the proposed rule because ozone is created by ultraviolet radiation and any ozone destroyed would allow play for more ultraviolet radiation to create additional ozone. Furthermore, ozone exists as a pollutant at the surface of the earth, and, since it is lighter than fluorocarbons, it is more likely than fluorocarbons to rise to the stratosphere to replenish the supply of ozone. The comment hypothesized that an "Upper Air Commission" had misread research results which show that ozone destroys fluorocarbons, not the reverse.

Ozone in the stratosphere is indeed constantly formed by ultraviolet radiation, but, the currently known information indicates that the stratospheric ozone would be destroyed by chlorofluorocarbons faster than it could be replenished by the action of ultraviolet radiation. The other theories advanced in this comment do not have general scientific support. The stability of chlorofluorocarbons, in contrast to ozone, enables them to survive in the troposphere and rise over time to the stratosphere, where, in a catalytic reaction, they can break down the ozone found there. The Commissioner is unaware of any "Upper Air Commission" and finds no basis for accepting the theory advanced in the comment that there has been a mixup in research results.

COMMENTS ON THE TEXT OF AND NEED FOR THE WARNING

27. A few comments objected to the use of the term "warning" in the proposed labeling statement and the identification of the type of risk posed by chlorofluorocarbons. Some urged that, at the most, there be a labeling statement that the product contains a chlorofluorocarbon, or that chlorofluorocarbons "may affect the upper atmosphere." The comments viewed these statements as sufficient to meet the thrust of the NAS Committee's recommendation that "informative labeling" about the presence of chlorofluorocarbons be included on products. In addition, the Commissioner's action in a notice published in the FEDERAL REGISTER of November 26, 1976 (41 FR 52078) proposing to change the nomenclature for cosmetic ingredient labeling, under 21 CFR 701.3, from a propellant designation to a chlorofluorocarbon designation was claimed to be sufficient to inform consumers about chlorofluorocarbons.

A separate label statement that simply states that a product contains a particular ingredient does not inform the con-

sumer of the risks associated with the ingredient, and of the reason for singling out the ingredient for mention. The statement could even be misconstrued as a claim that the presence of a chlorofluorocarbon enhances the value or desirability of the product. A statement that chlorofluorocarbons may affect the upper atmosphere does not apprise the consumer of the terrestrial consequences of the atmospheric effects which are the real cause for concern. Ingredient labeling, even with improved nomenclature, is not sufficient since all consumers may not recognize the ingredient of concern by name or be aware of the risks posed. Furthermore, an ingredient statement does not purport to be a warning.

In addition, a listing of inactive ingredients need not appear on products that are only drugs. Products that are cosmetics, or both cosmetics and drugs, would have to include the new nomenclature for chlorofluorocarbon propellants in the ingredient statement in accordance with a delayed effective date as established in the final rule. No cutoff can be established under the Fair Packaging and Labeling Act (15 U.S.C. 1454 et seq.) pursuant to which cosmetic ingredient labeling has been required, for initial introduction into interstate commerce, thus making the timing of the use of the new nomenclature more uncertain.

The NAS Committee recommended "informative labeling" as "an aid to consumer self-restraint * * * and to consumer preparation for possible later regulation." The Commissioner believes that a warning statement is likely to achieve these purposes more effectively than would a simple change in nomenclature in the statement of ingredients or a descriptive statement that the product contained certain ingredients. Accordingly, the Commissioner concludes that a warning statement is appropriate.

28. A comment suggested that the warning refer specifically to the risk of an increased incidence of skin cancer as a result of the effect of chlorofluorocarbons on the environment.

The suggested revision of the proposed text is not being made. The public is, understandably, exceptionally alarmed by risks of cancer. A reference to a cancer risk on the label should be accompanied by a careful explanation which may require a lengthy text. Furthermore, a reference specifically to cancer, even though stated to be an environmental effect, could without further explanation lead some consumers to believe the risk is greater for the individual user of the product, an implication that is not as likely with the reference to the "public health" in the warning established by this regulation. The public may be concerned about the past uses of self-pressurized containers and the consequences to the health of the immediate user. The brief warning established by this regulation informs the public of the general nature of the consequences of chlorofluorocarbon without alarming the public unwarrantedly about past individual exposures.

29. One comment urged a uniform Federal approach to labeling requirements because it might discourage a proliferation of diverse State labeling requirements about chlorofluorocarbon risks. It would be difficult for manufacturers to comply with diverse State labeling requirements in view of the national distribution of many products. Another comment urges prompt Federal regulatory action on aerosols containing chlorofluorocarbons to avoid a "crazy-quilt" of State laws requiring warnings and/or banning products that may be incongruent.

The Commissioner believes the comments have considerable merit. The Food and Drug Administration strongly encourages uniformity in the labeling requirements of State agencies and the Federal government. The issuance of the FDA warning may be accepted by State governments as adequate to satisfy their concerns. Thus, the interest in uniform labeling requirements provides additional grounds for issuing this regulation.

The Commissioner does not object to State laws or regulations prohibiting the use of chlorofluorocarbons in foods, drugs, devices and cosmetics or establishing an earlier date for the phaseout of the use of chlorofluorocarbons in these products within a State than the dates proposed by the Commissioner. State laws or regulations prohibiting use of chlorofluorocarbons are not in conflict with FDA's general objective of phasing out nonessential uses of chlorofluorocarbons, and these provisions do not pose the same risk of consumer confusion and disruption that may be presented by diverse label warning requirements. States may, however, find it unnecessary to take separate action to prohibit use of chlorofluorocarbons because of the action being taken by FDA.

The Food and Drug Administration agrees that uniformity among Federal labeling requirements is also desirable. As already discussed, however, FDA believes that a warning requirement is necessary rather than a descriptive statement of contents like the one EPA has established for pesticides. Federal labeling requirements apply to different products, and variations among Federal requirements do not increase the burdens on any individual manufacturer. Thus, there is not as great a need for uniformity among Federal requirements as there is between Federal and State requirements. Furthermore, since FDA regulates most of the uses of chlorofluorocarbons in self-pressurized containers, the establishment of a similar approach by FDA and the Safety Commission for the warning requirement may be sufficient to reduce the possibility of diverse State warning requirements with respect to chlorofluorocarbons.

30. Some comments asked that the proposed warning be required even on self-pressurized containers used for essential products containing chlorofluorocarbons. They thought the presence of the warning would give the manufacturer a continuing incentive to find alternatives to the use of chlorofluorocarbons.

The warning has not been required for products in which the presence of the warning might discourage consumers from using products that are essential. The Commissioner agrees that alternatives to the use of chlorofluorocarbons should be sought even for uses that are essential. Whenever alternatives become technically feasible, FDA will reconsider the regulations in effect governing the use of chlorofluorocarbons and all exemptions for essential uses. Furthermore, interested persons may request reconsideration of the exemptions at any time if they become aware of technically feasible alternatives.

31. Some comments suggested that the warning should indicate other risks posed by use of self-pressurized containers, including the risk of death from intentional misuse. One comment suggested that aerosols bear crossbones on the labeling to alert consumers to a risk of death from "irreversible heart action" after breathing fluorocarbons. The comment attributed several deaths of young people to this cause.

The risk of breathing fluorocarbons referred to in the comments appears to be the risk from intentional misuse of self-pressurized containers with hydrocarbon and halocarbon propellants. The FDA has already taken action with respect to this hazard and has required containers with these propellants to bear a warning about the risk of death from intentional misuse, e.g., 21 CFR 740.11.

32. Two comments urged that the warning advise use in a well-ventilated room and caution against use of self-pressurized containers containing chlorofluorocarbons by persons with chronic lung or heart disease. Another comment urged a ban because inhalation of chlorofluorocarbons may cause direct adverse physiological reactions for asthmatics and people who become sensitized.

The comments were directed at issues that are distinct from the concerns that prompted the proposed warning; therefore, those persons commenting should file a citizen's petition to propose a new rule to cover the hazards addressed in the comments, and the petition should include any data or studies they rely on to show that chlorofluorocarbons pose the risks described. The Commissioner points out that he discussed in detail in the document published in the FEDERAL REGISTER of March 3, 1975 (40 FR 8912) the evidence of various risks from aerosols to the immediate users. He gave his basis for concluding that the need for certain other warnings about cardiac toxicity and adverse effects on the pulmonary system had not been sufficiently demonstrated at that time.

33. Three comments argued that no warning should be required with respect to the risks from chlorofluorocarbons because it would dilute the effectiveness of other warnings that are required on products to alert consumers to more imminent hazards.

The Commissioner rejects the comments. The consumer should be alerted

to all the serious hazards posed by a product. While the impact of warnings might be reduced if numerous statements were included, the Commissioner concludes that the warnings on self-pressurized containers are not so numerous as to make the dilution effect an overriding concern at this time.

34. A number of the comments urging a phaseout came from school children. Some expressed concern that the adverse consequences of present uses would occur in the future and would affect them and future generations more than it would affect the adults who use the products now.

The Commissioner recognizes the fact that the ill effects of chlorofluorocarbons may fall more on future generations than on the present generation of users. This confirms the need to proceed with a mandatory phaseout rather than rely completely on voluntary self-restraint coupled with a warning.

HAZARDS FROM ALTERNATIVES

35. In one comment a beautician reported that in her personal experience as a beautician, alternative propellants and product delivery systems used for cosmetics in lieu of chlorofluorocarbons caused eye irritations and other adverse effects. The comment urged FDA to check on the safety of the alternatives and to consider whether the alternative products posed worse hazards than chlorofluorocarbons. The comment asked whether companies have a responsibility to test cosmetics for safety before marketing them. Several other comments expressed concern about the flammability of alternative hydrocarbon propellants.

The Commissioner recognizes that it is possible that alternative products may also pose hazards of various types. The present action relates only to the adverse effects of chlorofluorocarbons upon stratospheric ozone, and the potential physiologic hazards from other products are not within the scope of this regulation. It is the Commissioner's position that manufacturers should substantiate the safety of all their products before marketing, and under 21 CFR 740.10, cosmetic manufacturers are required to warn consumers if they have failed to perform testing to substantiate the safety of products. Furthermore, products must bear warnings necessary or appropriate to prevent a health hazard that may be associated with the product (21 CFR 740.1). If the adverse reactions associated with a product are unreasonable, in number or severity, FDA will take regulatory action. Citizens may petition FDA to take regulatory action with respect to any risk posed by regulated products. It would not be appropriate, however, to leave an unsafe product on the market, because the possible risks of alternatives were not yet fully known and might also be unacceptable. Instead, no unsafe products should be marketed. The Food and Drug Administration endeavors to ensure the safety of all cosmetics and products it regulates; FDA resources are limited, however, and in some instances, including with respect to cosmetics, FDA's statutory authority needs strengthening. Within these constraints, FDA will continue to act to ensure the safety of all the products subject to the FFDCA.

PLACEMENT AND SMALL CONTAINERS

36. Many comments urged the Commissioner to ensure that the warning was prominent by requiring it to appear on the front of the package, rather than on the back, and in type size at least ¼ inch in height. One comment pointed out that no minimum type size requirement exists for warnings on animal drugs.

The Commissioner agrees that the warning should be prominent, but he believes that the proposed requirement is adequate to ensure this result. The warning must be conspicuous at the time of purchase, and ordinarily this requirement could not be satisfied by putting the warning only on the back. The warning need not necessarily appear on the front of the package. For example, it may appear on the top of the cap, on a hang tag, or another place conspicuous at the time of purchase. A minimum 1/16-inch type size is required under the general regulations applicable to certain required labeling on foods and cosmetics, and warnings on OTC drugs in self-pressurized containers (21 CFR 101.15(d) (formerly 21 CFR 1.9(d), prior to recodification published in the FEDERAL REGISTER of March 15, 1977 (42 FR 14302)), 369.21, and 740.10). If this warning were required to be in a larger minimum type size, it would distract attention from other equally important warnings and information. The minimum type size requirements were fixed with regard to the small size of some containers and the various types of labeling information that is required to appear on packages.

In considering these comments, the Commissioner carefully reviewed the size and placement requirements in the proposal, and noted that, in the case of medical devices and animal drugs, no general minimum type size requirements now exist. Accordingly, he has amended the proposed regulation to make these products subject to the same minimum 1/16-inch type size requirement applicable to other products to which the regulation applies.

37. Two comments requested an exemption for "miniature" self-pressurized containers with 1 ounce or less of contents because of the length of the warning and the difficulties in fitting the warning into the space available on small containers.

The Commissioner anticipated the label space constraints inherent in small packages of self-pressurized containers and specified in the proposed rules that "the warning may appear on a firmly affixed tag, tape, cord, or sticker or similar overlabeling attached to the package." Although these alternatives involve additional expense, it is clear that they are practical means of labeling small self-pressurized containers.

38. A comment urged the Commissioner to require the proposed warning on both the immediate container and the labeling visible at the time of purchase.

The Commissioner adequately discussed in the preamble to the proposed rule his reasons for believing that a warning at the time of purchase would be sufficient. The comment provided no new information to alter the Commissioner's analysis.

GENERAL EXCEPTIONS FROM WARNINGS

39. Some comments expressed support for the Commissioner's decision not to make the warning applicable to prescription drugs and urged a similar exemption from the phaseout regulation.

The Commissioner accepts the comments with respect to the warning, but he is proposing to make the phaseout applicable to prescription drugs unless the use of chlorofluorocarbons in them is essential, as discussed further in the phaseout proposal.

40. One comment suggested that an exemption should be provided for medical uses, irrespective of their essentiality, because as a group the total amount of chlorofluorocarbons used for this purpose was small and would not pose a substantial risk. Other comments suggested that small packages of aerosol products, e.g., those having less than 1 ounce capacity, be exempted from the proposed warning statement requirement and the proposal to phase out nonessential uses of chlorofluorocarbons because the amount of chlorofluorocarbons released in the atmosphere by small aerosol packages amounts to only a fraction of 1 percent of the total amount of chlorofluorocarbons released.

The comments are not accepted. Various minor uses of chlorofluorocarbons may appear to present a minimal risk when considered individually but when cumulated the total becomes significant. Moreover, it would be inequitable to exempt a few uses on this basis apart from the essentiality of the use. The whole class of nonessential uses should be treated the same.

ESSENTIAL USES: GENERAL COMMENTS

41. A number of comments were addressed to the criteria for determining which products are essential and should not be phased out or required to bear a warning. It was suggested that the rule relating to the warning requirement contain a procedure for petitioning to have products exempted from the warning, and that the obligation to include a warning in labeling be stayed at least for OTC drug uses while such petitions were pending.

The final rule establishing the warning requirement indicates the products which are exempt as essential products. No special procedure has been included for obtaining additional exemptions from the warning requirement. The Commissioner has considered all the requests for exemptions received in response to the proposal and has discussed below his disposition of them. Persons who believe additional exemptions are warranted may file a citizen's petition under 21 CFR 10.30 (formerly 21 CFR 2.7, prior to recodification published in

the FEDERAL REGISTER of March 22, 1977 (42 FR 15553)), to amend the regulation. A stay of the regulations will not be granted absent an extraordinary showing that it is warranted. If a stay were routinely granted with the filing of a petition, numerous unwarranted requests might be made merely to obtain the benefit of the stay.

The phaseout proposal indicates that a product will be considered essential only if there is no technically feasible alternative to the use of the chlorofluorocarbon in the product, the product provides a substantial health benefit, environmental benefit, or other public benefit that would not otherwise be obtainable, and the use does not involve a significant release of chlorofluorocarbons into the atmosphere or the release is justified by the benefit. The same criteria guided essentiality determinations with respect to the warning. A procedure for requesting determinations that a product is essential has been included in the phaseout proposal. It is appropriate to include such a procedure in the phaseout regulation, even though it is not in the warning regulation, because of the indefinite long-term effect of the prohibition and the possibility that new products providing life-saving or other essential benefits may be developed. The criteria for essentiality are similar for both the phaseout and the warning. The Commissioner notes, though, that there is less reason to regard products as exempt from the warning, since the warning does not prevent marketing or use of products.

42. One comment criticized the Commissioner's criteria for essentiality, insofar as they applied to the warning and the phaseout, since they did not recognize that a product may be essential because it "confers unique benefits because of its aerosol form." In addition, several comments criticized the Commissioner's determination that most products in self-pressurized containers are nonessential, and mentioned the consumer preference for self-pressurized containers, exactness of dose, and longevity of storage as factors showing essentiality.

The Commissioner believes the essentiality criteria provide for an appropriate recognition of all factors that may make a product essential. A self-pressurized container could be considered essential if the form conveys a substantial benefit not obtainable from alternate means of delivery. The Commissioner still finds that almost all uses of chlorofluorocarbons as propellants in FDA-regulated products are not essential, but serve principally as conveniences. Counterparts to self-pressurized containers exist that perform essentially the same function. The application of the essentiality criteria to specified products raised in the comments is discussed below.

43. Several comments requested that all OTC drug manufacturers using chlorofluorocarbon propellants in their drug products be permitted to continue marketing such products without the necessity of a warning statement until the chlorofluorocarbon ban becomes effective. It was asserted that all OTC drugs in self-pressurized containers confer a benefit which far outweighs the relative risk of environmental harm, especially since the use of chlorofluorocarbons in OTC drug products constitutes such a small percentage of chlorofluorocarbon propellant use. In addition, these comments emphasized the essential part that OTC drugs play in our health-care system. Alternatively, the same comments suggested that all OTC "medicines" containing chlorofluorocarbons that confer a health benefit or that provide more than consumer convenience be exempt from the warning statement. Another comment supported an exemption for medical products in which the dose delivered is significant.

As stated in the preamble to the proposed warning statement, the warning is being proposed for virtually all uses of chlorofluorocarbons in self-pressurized containers because most uses are, in the Commissioner's judgment, not essential. Therefore, the Commissioner cannot accept the suggestion to exclude all OTC drugs from the warning statement because it is obvious that not all chlorofluorocarbon uses in OTC drugs are essential. Antiperspirants, for example, are OTC drugs because of their effect on the structure and function of the body, and a self-pressurized package is not essential for these products. In fact, even the comments acknowledge in their alternative suggestion that the use of a self-pressurized container for some OTC drugs provides merely a convenience and not a health benefit.

The fact that the use of chlorofluorocarbon propellants in OTC "medicines" is estimated by the comments to be small—about 3 percent—of the total amount of chlorofluorocarbon propellants used in FDA-regulated products is not the only criterion to be used in determining whether or not the warning statement should appear on OTC drugs. In addition to the amount of chlorofluorocarbons used, the issues of feasible alternatives to the use of chlorofluorocarbons and the benefit, if any, derived from the use of the chlorofluorocarbons must be considered. If the dose delivered is significant, and other systems cannot provide an equivalent control of the dose, this would be an important factor in establishing that a specific product is essential. If suitable alternatives exist, however, or if there is no significant benefit derived from the use of the chlorofluorocarbon, the warning statement is appropriate despite the fact that the amount of chlorofluorocarbon used in the product is quite small.

Likewise, the inclusion of the warning statement on certain OTC drugs does not imply that these OTC drugs are not an essential part of our health system. It merely means that the use of chlorofluorocarbons in the product containing the warning is nonessential, i.e., that other suitable means of product delivery exist and the products themselves, in a self-pressurized container, serve only as a convenience, providing no special benefits that outweigh the risks posed.

Furthermore, the distinction between OTC drug products that are "medicines" and those that are not, is a distinction suggested by the comments, whose meaning is uncertain. The amount of chlorofluorocarbons in the "medicines" category depends upon the meaning to be given to the term. If a product were to be considered a "medicine," and therefore exempt from the warning and phaseout merely because it made a therapeutic claim, it could lead to a proliferation of questionable claims.

The Commissioner concludes that an OTC drug product should be exempt from the warning statement only if it is determined by FDA that the use of a chlorofluorocarbon propellant in the specific product is essential.

Each comment received requesting an exemption for a specific OTC drug product or class of OTC drug products from the warning statement or the phaseout has been considered and discussed below in determining what OTC drug products should be exempt from the warning statement. The Commissioner has also discussed below comments on the notice of intent that bore on the essentiality of prescription drugs, even though prescription drugs are not subject to the warning, if the essentiality issue for the prescription drug was similar to that for an OTC drug.

ESSENTIAL USES: SPECIFIC PRODUCTS

44. In addition to several comments requesting that all OTC drug products be exempted from the warning statement, many other comments requested that one or more specific OTC drug products, or classes of OTC drug products, be exempted from the warning statement. Many of these same comments also requested that a specific product or class of products, be exempted from the phaseout regulations. Some of the types of drug products covered by these comments include: topical analgesics, sunburn remedies, topical antimicrobial agents, insect bite products, topical antifungal agents, surgical spray dressings, and topical anti-inflammatory agents. The comments argued that the benefits of the products for human health far outweigh the problem of ozone depletion. Many of the comments stressed the unavailability of suitable replacements for the chlorofluorocarbon propellants, the small amount of these propellants used in drug products, and the efficient, nontraumatizing mode of application afforded by aerosols. Some of the comments also pointed out that the possibility of secondary infections, present when an ointment or lotion had to be applied with the fingers, would be greatly reduced.

With respect to many of the products identified in the comments, the Commissioner believes that having the drug in a self-pressurized container is a convenience to the user. For example, it is recognized that using a self-pressurized container is not as messy as applying an ointment or cream. The fact that the drug is available in other delivery forms

indicates, however, that the aerosol dosage form is not necessary for the drug to achieve its desired effect. Even the aerosol drug products used to treat skin infections are available in other dosage forms. Thus, it would appear that manufacturers have not considered the possibility of secondary skin infections to be of such a concern to preclude their marketing of these other dosage forms.

The active ingredients of many of the drug products for which an exemption was requested are currently being sold in other forms, such as ointment, lotions, creams, and powders. Thus, it appears that other forms of product delivery exist. Further, it would seem that for some of these products where the actual amount of active ingredient delivered is not critical, an alternative propellant or a mechanical pump could be used in place of the chlorofluorocarbon. Accordingly, the Commissioner concludes that the essentiality of their use has not been established.

45. Several comments requested that drugs in self-pressurized containers intended for inhalation in the treatment of bronchial asthma be declared essential and thus exempt from both the warning requirement and the proposed phaseout regulations. The products mentioned in the comments were either steroid-containing products or OTC and prescription adrenergic bronchodilator drug products. One comment requested that "all metered-dose medicinal aerosols for inhalation therapy" be exempted from the phaseout regulations. Another comment requested that metered-dose steroid aerosol products intended for application to the nasal mucosa be exempted. One comment urged that the exemption in the proposed rule for drugs intended for "bronchial asthma attacks" be broadened to include a prophylactic inhalant used to prevent asthmatic attacks.

Justifications included in these comments for the continued use of chlorofluorocarbons in products for inhalation centered around several different facts. The first fact was that, unlike other commercially available propellants, the chlorofluorocarbons maintain a constant internal canister pressure throughout the shelf life of the product. As a result, a self-pressurized container containing a chlorofluorocarbon can deliver a potent therapeutic drug in precisely metered doses, with the last dose containing the same quantity of drug as the first dose. Further, these drugs, because of their cholorofluorocarbon propellant, provide a uniform distribution of the therapeutic agent in small particle size to hard-to-reach mucous membranes. Application of these therapeutic agents in this manner achieves the therapeutic objective with lower doses of medication than do systemic doses. Another factor cited in support of these products is that other forms of the product do not produce the same clinical effect.

The Commissioner recognizes the importance of chlorofluorocarbons in providing effective metered doses for use in inhalation therapy of certain diseases and, in general, accepts these comments. He does not, however, believe that an exemption should be worded as broadly as "all metered-dose medicinal aerosols for inhalation therapy." Such a broad exemption would cover products even if another suitable form of product delivery exists for the treatment of the particular disease for which the drug is recommended. The Commissioner believes, therefore, that the proposed exemptions should not be in broad terms but should assure that only essential uses of self-pressurized containers with chlorofluorocarbon propellants are exempted.

Based on the comments received, the Commissioner is proposing that the following metered-dose drug products for inhalation be considered essential: (1) Metered-dose steroid products for nasal inhalation, (2) metered-dose steroid products for oral inhalation for treatment of bronchial asthma, and (3) metered-dose adrenergic bronchodilators for oral inhalation for treatment of bronchial asthma. The first two types of metered-dose aerosols are all prescription drugs. Some products in the third category are OTC products, while others are prescription products, depending upon the active ingredient. The Commissioner is exempting all these products from the proposed phaseout. The warning requirement does not apply to prescription drugs. As proposed, the warning requirement exempted OTC drugs intended for direct inhalation for treatment of bronchial asthma attacks. However, to be more specific, the Commissioner now believes that this class of products should be identified as metered-dose adrenergic bronchodilators for inhalation. The regulation has been revised accordingly.

The prophylactic inhalant to prevent asthma attacks referred to in one of the comments is a prescription drug which would not be subject to the warning requirement. The Commissioner agrees the use is essential and it is covered by an exemption in the proposed phaseout regulation for metered-dose steroid drugs for inhalation.

46. One comment requested that the proposed warning statement exemption for OTC drugs be broadened to include "metered-dose aerosols for medicinal therapy." The comment neither identified any specific product covered by such a phrase nor did it indicate if such products were OTC or prescription products. The comment did, however, refer to the successful use of a metered-dose aerosol drug product containing a decongestant as a substitute for a plastic squeeze bottle. By using the metered-dose aerosol product, the comment indicated that the possibility of contaminating the contents of the squeeze bottle through mucous and associated bacteria being drawn back into the container would be eliminated.

The Commissioner recognizes the essentiality of metered-dose aerosols for delivering certain drugs. As stated above, OTC metered-dose adrenergic bronchodilators for inhalation have been exempted from the warning statement. The Commissioner concludes, however, that not every OTC drug in a metered-dose aerosol would necessarily constitute an essential use of chlorofluorocarbons. Some of these products could be in a metered-dose aerosol form merely for convenience purposes. Therefore, the comment as submitted is not accepted. It is noted, however, that, in addition to being used for OTC drug products, metered-dose aerosols are also used for prescription drugs, and as already discussed, several types are considered to be essential and are exempt from the proposed phaseout.

With respect to the alleged advantage of a self-pressurized container over a squeeze bottle for nasal application, the Commissioner is not aware of any contamination problems associated with squeeze bottles, possibly because most of the nasal sprays in squeeze bottles contain a bacterial preservative. However, if such contamination of nasal sprays in squeeze bottles is presently a problem, comments should be submitted on this issue on the proposed rule to phaseout chlorofluorocarbon propellant uses. Therefore, the comment as submitted is not accepted.

47. Three comments requested that OTC contraceptive vaginal foams be exempt from the phaseout regulations and/or from the warning statement. These comments indicated that the chlorofluorocarbon propellants are currently the only available propellants that achieve foams of proper consistency and stability. It was stated that the foam drug products are dependent upon two characteristics to achieve their contraceptive effect: one the active spermicidal agent, and the other the physical barrier provided to the cervical os due to the consistency of the foam. In addition, it was emphasized that contraceptive foam products are an essential form of birth control for a segment of the population, and the use results in very little release of chlorofluorocarbons to the atmosphere since these products contain 10 percent or less of chlorofluorocarbons.

The Commissioner agrees that contraceptive vaginal foams should be exempted from the proposed phaseout regulations. While other contraceptive methods exist, the contraceptive vaginal foams provide a method, available over the counter, that is found acceptable by a small select population of females. No satisfactory substitute propellant has been found to date according to the submissions, and there is the risk of reduced effectiveness or safety of the product through use of the wrong propellant. In the absence of another suitable delivery system for applying these spermicidal agents, the Commissioner concludes that in view of the benefit of the contraceptive vaginal foams that would not be obtainable without the chlorofluorocarbons and the small amount of propellant used, these products should be exempt from the proposed phaseout regulations and from the warning statement required on nonessential uses of chlorofluorocarbons.

48. Two comments urged the Commissioner to determine that cytology fixa-

tives, medical adhesive sprays and removers, pre-tape sprays and surgical lubricants are essential and that their health benefits far outweigh the ozone depletion risks. One comment indicated that the only available alternative propellants that would function properly in the cytology fixative and other sprays were flammable and introduce a usage hazard in hospital, clinic, and laboratory environments.

The cytology fixative spray results in a superior tissue preparation, especially in the preparation of Pap smears. The Commissioner concludes that this use should be regarded as essential, and it has been exempted from the warning and the proposed phaseout. The comments did not provide sufficient information however, to establish that any of the other devices discussed in these comments are essential. The use of a self-pressurized container to apply medical adhesives, lubricants, and other substances appears to be a convenience and alternative means of application are possible, e.g., liquid adhesives for topical application. Accordingly, these uses of chlorofluorocarbon propellants will be subject to the warning requirements, and are proposed to be phased out, but the Commissioner will consider further information submitted in response to the phaseout proposal that relates to whether these uses are essential.

49. One comment declared that certain personal hygiene aerosol products, including foot powder spray and foot and shoe cooling sprays, are "important in terms of personal comfort, antiperspirant and deodorizing activity for feet." Continuing to market these products was reported as essential to the company's economic well being.

The Commissioner does not disagree with the contention that the personal hygiene products named may be important to some persons for comfort, but alternate delivery systems are available for these products, e.g., powders. No alternatives may exist that provide the equivalent coolant effect, but this effect is a temporary convenience, and interrelated with the propellant use.

50. One comment inquired about the applicability of the warning requirement to prescription animal drugs, and another comment urged that prescription drugs considered essential for human use be deemed essential as animal drugs as well.

The Commissioner intends to make the regulation applicable to all animal drugs. Essentiality requires an examination of alternatives and the benefits of use of products and these factors may vary with the circumstances. No specific information was submitted to show that any particular animal drugs in self-pressurized containers with chlorofluorocarbon propellants were essential, and accordingly, no exceptions have been made for animal drugs. Any person who believes a use is essential should submit comments in response to the proposed phaseout showing why the particular use is believed to be essential under the criteria stated in the proposal.

TIMING OF REGULATORY ACTION; EFFECTIVE DATE

51. Several comments specifically supported the Commissioner's decision to initiate regulatory action at this time without waiting for up to 2 years, as recommended by the NAS Committee, for additional research. As already discussed, other comments urged a delay to await further research. Still other comments expressed a strong preference for immediate regulatory action, with several comments expressly endorsing an immediate ban on use of chlorofluorocarbons. Some comments, favoring an immediate ban, disagreed with the proposal to require a warning on the grounds that a warning would be futile and/or delay a ban.

The Commissioner disagrees with the comments to the extent they urged immediate action without observance of the usual notice-and-comment procedures for issuing rules. Observance of these procedures is consistent with the IMOS Task Force recommendation that agencies initiate regulatory action at present so that thorough and thoughtful action could be given to the action. Furthermore, an immediate ban would not have permitted preparation of a draft environmental impact statement for the phaseout, and coordination of the ban with other Federal agencies. The Commissioner also believes that a reasonable period for a phaseout should be permitted; accordingly, he has not proposed an immediate ban. In the Commissioner's judgment, the warning will be helpful in reducing uses on an interim basis, and it will become effective shortly.

52. A few comments urged that regulatory action be delayed until alternative hydrochlorofluorocarbon propellants are available, or it is definitely known that they are unsafe and would not be marketed in the future for personal care products. They viewed hydrocarbon propellants as undesirable in terms of product performance, consumer preference and the increased risks of flammability. Rather than have aerosol fillers cease to make aerosol products or switch to hydrocarbons, only to switch again at extra cost to hydrochlorofluorocarbons if they became available, FDA was urged to wait "a little more time" for the completion of toxicological testing on hydrochlorofluorocarbon propellants that could be used as substitutes for chlorofluorocarbon propellants. A comment stated without explanation that more information on the toxicity of hydrochlorofluorocarbons would be available within 90 days.

DuPont, a leading producer of hydrochlorofluorocarbons, has reported (Ref. 40) that adverse toxicological findings were found for certain hydrochlorofluorocarbons in initial screening tests for mutagenicity and/or teratogenicity. As a result, long-term inhalation studies were planned and "in all likelihood" the company will not offer certain hydrochlorofluorocarbons for use in personal products until "approximately January 1, 1980." Information was also submitted to show that hydrochlorofluorocarbons do not pose a significant risk of causing ozone depletion or other adverse environmental effects.

A delay to await the availability of alternative hydrochlorofluorocarbon propellants is likely to involve a considerable delay well into 1980, with no assurance that the alternatives would be found to be safe and available. Alternative product delivery systems, such as pumps and nonspray products, already exist for most products in self-pressurized containers using chlorofluorocarbons. Accordingly, the Commissioner concludes that a delay to await further testing of hydrochlorofluorocarbons that may possibly be used as substitutes is not warranted.

53. One comment from an industry association reported that the use of chlorofluorocarbon propellants in self-pressurized containers is declining and that today two-thirds of all aerosols on the market use other propellants. The comment suggested that this decline in use warranted postponement of all regulatory action.

The Commissioner believes that the decline in the use of chlorofluorocarbon propellants is a welcome development. Other reports indicate that there has been a decline in the use of chlorofluorocarbon propellants (Ref. 41). The Commissioner also recognizes that alternative product delivery means are being extensively promoted and as a result, the use of chlorofluorocarbon propellants may decline further. The switch to alternatives by manufacturers may be in anticipation of the issuance of the final rule requiring the warning and the effect a warning will have on consumer purchases. If the Commissioner indicated he would withhold all regulatory action for a considerable period, the decline may cease. Thus, the present decline is not a justification for postponing all action.

The decline in use of chlorofluorocarbon propellants is, however, a development which is relevant in establishing an effective date for the warning requirement. Under the proposed regulation, the warning would have been required on products initially introduced into interstate commerce 30 days after the final rule was issued. This time span was short, and it was recognized that it would necessitate costly overlabeling, and perhaps some distribution difficulties, but it was believed necessary to require fast implementation of the warning requirements so that consumers could become aware of the risk and, through their purchasing decisions, reduce the use of chlorofluorocarbon propellants. At the time the regulation was proposed, it was not possible to foresee the extent to which industry would promote alternative product delivery means, apparently in anticipation of the potential consumer reaction to the warning.

The Commissioner believes that his basic aim of reducing nonessential uses of chlorofluorocarbon propellants is being achieved even before the final rule requiring a warning becomes effective. Accordingly, it is possible, consistent with the overall aim of reducing use, to extend the time for complying with the warning requirement. By extending the effective date, the warning can be implemented

with a lesser amount of costly overlabeling, and with less potential for disruption in distribution, as discussed further below. The establishment of a final rule requiring a warning with a fixed effective date in the relatively near future, will maintain the incentive manufacturers have to develop and promote alternative delivery systems in anticipation of the consumer reaction to the warning. Thus, despite the extended time to comply with the warning, the warning requirement can still be expected to achieve its basic purpose of reducing use in the interim, pending a phaseout.

54. A number of comments strenuously objected to the Commissioner's proposal to require the warning on all products labeled or initially introduced into interstate commerce on or after 30 days from the issuance of a final rule requiring a warning. The effective date was viewed as especially onerous to the extent it would have required additional labeling on fully labeled products in inventory. Some comments asserted that the effect of the proposed 30-day effective date was to deprive companies of their right to comment since the only way to comply with the requirement, if retained, would be to order complying labels even before a final rule was adopted.

The comments also urged that the warning be required only on new permanent labeling ordered after the effective date, and that no requirement be imposed that would necessitate the use of stickers. Stickers were described as impractical because of poor adhesives and expense.

In support of these views, a trade association submitted a survey of its members of the cost of and time needed for compliance with the requirement for warning labeling. The time to label existing inventory with stickers or other overlabeling was estimated to be between 5 and 31 weeks, with most companies requiring more than 11 weeks. The direct cost was estimated at between 6 and 8 million dollars, and it was reported that many companies would have to suspend shipments for a month or more resulting in lost sales. The time estimates were made in relation to "ideal conditions." If all companies were placing rush orders at the same time, the time would be greater, and might even double. Another comment considered anything less than 6 months to sticker existing inventory to be "impossible."

The direct cost of labeling new production with stickers was estimated to be nearly $3 million. The trade association estimated that between 4 and 15 weeks would be needed for companies to be prepared to apply stickers to new production, with most companies being ready in 11 weeks. It was reported that some companies would have especially severe difficulties in complying because they did not have machines on hand to apply overlabeling.

The survey also included estimates of the time needed to include the warning in a permanent labeling change. The total time for processing a permanent labeling change under ideal conditions from art work through initial shipment of a newly labeled product in interstate commerce was estimated as varying from 6 weeks to over 45 weeks, with two-thirds of the companies needing about 6 months. It was noted that the length of time between production and interstate shipment was long in some instances because some manufacturers produce a year's supply at a time and inventory it for shipment.

The comments urged several different schedules for putting the warning requirement into effect, with most supporting a 30-day effective date for ordering labeling, 6 months for labeling products, and 12 months for initial introduction into interstate commerce. It was noted that an early effective date would have a relatively greater impact on smaller companies.

The Commissioner is persuaded that the 30-day effective date would impose unusual practical difficulties particularly with respect to stocks of fully labeled containers on hand. Accordingly, he has changed the effective date provision to minimize the need to overlabel existing inventory. The warning will be required on all products initially introduced into interstate commerce 6 months after the date of publication of this final rule. Most companies can complete a permanent labeling change within 6 months according to the industry survey.

Use of some stickers or other overlabeling may nonetheless still be necessary for some companies. This will particularly affect products, for which a large supply is produced at a single time, to achieve economies of scale, with shipments being made throughout a later period. The entire existing inventory does not, however, have to be overlabeled before the effective date. The companies need only relabel the amount about to be introduced into interstate commerce. The comments did not indicate how much time was needed to meet current distribution requirements and maintain distribution on a continuing basis. The Commissioner believes 6 months should be reasonably adequate for this purpose.

Setting the effective date earlier than 6 months might increase the impact on products with heavier sales in the Christmas season which are ordinarily shipped into interstate commerce several weeks in advance. An earlier date would, though, necessitate increased use of stickers and other overlabeling on these products as well as on many other products that do not have this type of seasonal pattern.

The Commissioner rejects the suggestion that a 12-month effective date for compliance be established for products initially introduced into interstate commerce. The establishment of an effective date for initial introduction into interstate commerce is important to prevent stockpiling of noncomplying products by manufacturers for delayed shipment. While a 1-year effective date would virtually eliminate the need for any overlabeling, it would delay inordinately the appearance of the warning on all newly shipped products. This could reduce the incentive manufacturers presently have to develop alternative products. If the effective date were set at the maximum period the slowest company needed to implement permanent labeling changes, it would delay the warning a considerable time and long past the time most producers would need to include the warning in labeling. Accordingly, the effective date has been set at 6 months since by this date many companies can include the warning in permanent labeling, with no need to overlabel, and those companies who cannot complete a permanent change within 6 months should be able to overlabel their remaining inventory without inordinate difficulty.

The Safety Commission staff has also attempted to minimize the need for overlabeling in developing its recommendations for an effective date for the warning labeling that the Safety Commission proposes to require (Ref. 42).

Initial introduction into interstate commerce of a finished product for purposes of this regulation means the first shipment of the product into interstate commerce by the firm marketing the product. There must be both physical movement in interstate commerce, and passage of title to the product. Thus, mere shipment of a product across State lines from a contract filler to the manufacturer of the product would not constitute initial introduction into interstate commerce. All products initially introduced into interstate commerce before the effective date may continue to be distributed and sold even though they do not bear the warning statement. A finished product is a product which has been completely manufactured, packaged, and labeled.

55. One comment criticized the warning proposal because the time schedule for comments did not allow time for comments on a study being done by International Research and Technology Corporation and Policy Models, Inc., (IRT Study) under contract with EPA, on the economic impact of a phaseout of chlorofluorocarbons propellants. The Commissioner also received two requests that additional time be allowed for the submission of comments on the draft Policy Models, Inc., study. The Commissioner extended the time for submission of comments to the docket for the notice of intent on the draft report done for EPA. One of the associations requesting the extension subsequently submitted a late comment to the docket for the proposed warning stating that "we reserve the right" to submit comments to FDA on the final report assessing the economic impact of a phaseout.

The Food and Drug Administration has prepared an inflation impact statement of the phaseout of chlorofluorocarbon propellants being proposed by FDA. The statement was developed, in large part, on the basis of the data reported in the IRT Study. Comments may be submitted on the FDA inflation impact statement to the docket for the proposed phaseout. In developing its phaseout proposal, FDA considered the comments on the draft IRT Study sub-

mitted in response to the grant of an extension of time to comment. The Commissioner notes that the submissions emphasized the economic impact reported in the IRT Study and the many uncertainties facing the aerosol industry about the safety and feasibility of potential substitute propellants. This information essentially duplicates the timely comments submitted on the warning proposal, which have been discussed above in this document.

The Food and Drug Administration prepared an inflation impact assessment for the warning requirement at the time of the proposal, and considered the relevant comments submitted. Furthermore, the phaseout action being proposed by FDA will subsume whatever inflation impact the warning will have in reducing use of chlorofluorocarbon propellants. The agency's inflation impact statement for the proposed phaseout evaluates the impact comprehensively for the overall action being taken. Thus, the Commissioner concludes that with respect to the warning he has adequately fulfilled his obligations under Executive Order No. 11821, OMB Circular A-107 and HEW guidelines to consider the inflation impact of regulatory actions.

MISCELLANEOUS COMMENTS

56. A few comments urged action to prevent advertising of products containing chlorofluorocarbons.

The Commissioner has no jurisdiction over advertising, except for advertising for prescription drugs, products that are not subject to the warning requirement. He points out that when use is prohibited, advertising to promote the products can be expected to cease.

REFERENCES

1. Letter dated October 26, 1976 to Dr. Robert Schaffner from J. J. Daly, of E. I. duPont de Nemours and Co.

2. Molina, M. J. and F. S. Rowland, "Stratospheric Sink for Chlorofluoromethanes—Chlorine Atom—Catalyzed Destruction of Ozone," *Nature*, 249:810–812, June 28, 1974.

3. Wofsey, S. C., et al., "Freon Consumption Implication for Atmospheric Ozone," *Science*, 187:535–537, February 14, 1975.

4. Federal Task Force on Inadvertent Modification of the Stratosphere, "Fluorocarbons and the Environment," Chapter, V, June 1975.

5. Klauder, D. S., "Fluorocarbons in Aerosol Products Subject to the Jurisdiction of the Food and Drug Administration," 1976, unpublished staff memorandum.

6. Petition dated July 31, 1975 from Natural Resources Defense Council (NRDC) et al. to the Commissioner of Food and Drugs, Docket No. 75P-0192.

7. Letter dated September 8, 1975 from Alexander M. Schmidt, Commissioner of Food and Drugs, to Thomas B. Stoel, Jr., of NRDC, Docket No. 75P-0192.

8. National Academy of Sciences Committee on Impacts of Stratospheric Change, "Halocarbons: Environmental Effects of Chlorofluoromethane Release," 1-1 to 1-10, 8-15, 1976.

9. National Academy of Sciences, Committee on Impacts of Stratospheric Change, Panel on Atmospheric Chemistry, "Halocarbons: Effects on Stratospheric Ozone," 1976.

10. National Academy of Sciences, Climatic Impact Committee, "Environmental Impact of Stratospheric Flight," 41-45, 1975.

11. Memorandum dated September 24, 1976 to Russell W. Peterson, Chairman, Council on Environmental Quality from the Co-chairman of the Interagency Task Force on Inadvertent Modification of the Atmosphere.

12. Maugh, "The Ozone Layer: The Threat from Aerosol Cans is Real," *Science*, 194:170–172, October 8, 1976.

13. Petition dated October 26, 1976 from NRDC et al. to the Commissioner of Food and Drugs, Docket No. 76P-0456.

14. Letter dated October 15, 1976 to Ms. Carroll Bastian from F. S. Rowland.

15. PR Notice 76-3 dated October 18, 1976 from United States Environmental Protection Agency, Registration Division, to Producers, Formulators, and Registrants of Pesticides.

16. Arthur D. Little, Inc., "Preliminary Economic Impact Assessment of Possible Regulatory Action to Control Atmospheric Emissions of Selected Halocarbons," prepared for U.S. Environmental Protection Agency, EPA Contract No. 68-02-1349, Task 8, ADL 76072-80, Tables II-3, II-5, III-13, III-15 and pages III-6 to III-11, IV-4, IV-14, 1975.

17. Letter dated October 12, 1976 to Russell W. Peterson, chairman, Council on Environmental Quality, from Alexander M. Schmidt, Commissioner of Food and Drugs.

18. Minutes of the January 6, 1977 Meeting of the Consumer Product Safety Commission.

19. Statement of Russell E. Train, Administrator of EPA, in Hearing before the Subcomm. on the Upper Atmosphere of the Comm. on Aeronautical and Space Sciences, U.S. Senate, 94th Cong., 2d Sess., 23-40 (1976).

20. Memorandum of Law Submitted by CTFA in Opposition to the New York State Department on Environmental Conservation's Proposed Regulations for Chlorofluorocarbon Compounds, pp. 23-30 (November 21, 1975). The preemption argument was also made in *Chemical Specialties Manuf. Assn* v. *Berle*, Complaint for Declaratory Judgment p. 9-10 (Civ. Action No. 76-CV-199 (NDNY 1976)).

21. Memorandum dated November 26, 1976 for S. John Byington of CPSC, Alvin Alm of EPA, and Sherwin Gardner of FDA from Steven D. Jellinek, Staff Director of the Council on Environmental Quality.

22. Minutes of the November 22, 1976 Meeting of the Consumer Product Safety Commission, a copy of which appears in Hearing before the Subcomm. on the Upper Atmosphere of the Comm. on Aeronautical and Space Sciences, U.S. Senate, 94th Cong., 2d Sess., 398 (1976).

23. Conference Report to accompany S. 3219, H.R. Rept. No. 94-1742, 94th Cong., 2d Sess., 33-39, 98-99 (1976).

24. Statement and written answers of John W. Tukey in Hearing before the Subcomm. on the Upper Atmosphere of the Comm. on Aeronautical and Space Sciences, U.S. Senate, 94th Cong., 2d Sess., 5, 8, 16, 17 (1976).

25. National Aeronautics and Space Administration, Goddard Space Flight Center, "Chlorofluoromethane Assessment Workshop Report," iii-viii, 1-6, (Preliminary) (March 1977).

26. Statement of J. Peter Jesson in Hearing before the Subcomm. on Upper Atmosphere of the Comm. on Aeronautical and Space Sciences, U.S. Senate, 94th Cong., 2d Sess., 184-186 (1976).

27. Testimony and written answers of H. S. Gutowsky, January 3, 1977, in Hearing befor the Subcomm. on Upper Atmosphere of the Comm. on Aeronautical and Space Sciences, U.S. Senate, 94th Cong., 2d Sess., 18-22 (1976).

28. Singh, H. B., Stanford Research Institute (California), February 17, 1977, Personal communication.

29. Notice of Intent (Docket No. 76N-0460), Comment C0053, (Chou, C. C., R. J. Milstein, W. S. Smith, H. Vera Ruiz, M. J. Molina, and F. S. Rowland, "Stratospheric photodissociation of several saturated perhalo chlorofluorocarbon compounds in current technological use (fluorocarbons-13, 113, 114, 115)," Department of Chemistry, University of California, Irvine, California.)

30. Notice of Intent (Docket No. 76N-0460), Comment C0051 (Howard, Carleton J., and K. M. Evenson, "Rate constants for the reactions of OH with CH_4 and fluorine, chlorine, and bromine substituted methanes at 296 K," NOAA, Aeronomy Laboratory in Boulder, Colorado; Howard, Carleton J., and K. M. Evenson, "Rate constants for the reactions of OH with ethane and some halogen substituted ethanes at 296 K," NOAA, Aeronomy Laboratory in Boulder, Colorado; and Howard, Carleton J., "Rate constants for the gas-phase reactions of OH radicals with etbylene and halogenated ethylene compounds," NOAA, Aeronomy Laboratory in Boulder, Colorado.)

31. J. Angell (NOAA), February 28, 1977, Personal communication.

32. Letter dated February 17, 1977 to D. S. Klauder from B. Goldberg, Radiation Biology Laboratory, Smithsonian Institution.

33. Letter dated October 28, 1976 to A. M. Schmidt, former Commissioner of Food and Drugs, from H. S. Gutowsky, Professor, University of Illinois.

34. Letter dated December 8, 1976 to H. S. Gutowsky, Professor, University of Illinois, from S. Gardner, Acting Commissioner of Food and Drugs.

35. Fears, T. R., J. Scotto, and A. Schneiderman, "Skin Cancer, Melanoma, and Sunlight," American Journal of Public Health, 665:461-464, 1976.

36. Green, A. E. S., "A comment on 'Skin Cancer, Melanoma, and Sunlight,' " American Journal of Public Health, 671:59-60 (1977).

37. Rundel and Nachtwey Model for Ultraviolet Radiation and Non-melanoma Skin Cancer, Appendix A to FDA Draft Environmental Impact Statement, "Fluorocarbons: Environmental and Health Implications."

38. Edwood, J. M. and J. A. Lee "Recent Data on the Epidemiology of Malignant Melanoma," Seminars in Oncology, 2:149-154, 1975.

39. Biggs, R. H., W. B. Sisson, and M. M. Caldwell, 1975. "Response of higher terrestrial plants to elevated UV-B irradoamce," in "Impact of Climatic Change on the Biosphere, Part I, Ultraviolet Radiation Effects," pp. 4-34, 4-48, Nachtwey, D. S., Caldwell, M. M., and Biggs, R. H., eds., U.S. Department of Transportation DOT-TST-75-55, Washington, DC (1975).

40. Letter dated March 1, 1977 to Glenn E. Schweitzer, EPA, from Charles F. Reinhardt, E. I. DuPont de Nemours & Company, and comment No. 0021 submitted on the Notice of Intent (Docket No. 76N-0460).

41. "Chlorofluorocarbon Aerosols: Will There Be Any to Regulate?", Modern Packaging 50:18-19, January 1977; "Hydrocarbon Aerosols Make it on Merits," Chemical Week, 120(4):23, Jan. 26, 1977; "They're Putting Sweat into Package," Chemical Week, 119 29-32, December 8, 1976; "Likely Fluorocarbon Ban Causes Makers of Aerosols to Promote Other Propellants," Wall Street Journal, Dec. 24, 1976; International Research and Technology Corporation and Policy Models, Inc., "The Economic Impact of Potential Regulation of Fluorocarbon Aerosols," 2-1 to 2-21 (1977).

42. Memorandum dated April 6, 1977, from Walter R. Holsky and Arlen J. Slobodow through Joann Langston to Elaine Besson re Section 27(c) Regulation Requiring Labeling of Chlorofluorocarbon Propellants.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(n), 301, 402, 403, 501, 502, 505, 507, 512, 601, 602, 701(a), 52 Stat. 1041–1043 as amended, 1046–1048 as amended, 1049, 1051–1053 as amended, 1054–1055, 57 Stat. 463 as amended, 82 Stat. 343–351 (21 U.S.C. 321(n)), 331, 342, 343, 351, 352, 355, 357, 360b, 361, 362, and 371(a))) and the National Environmental Policy Act of 1969 (sec. 102(2), 83 Stat. 853 (42 U.S.C. 4332)), and under authority delegated to the Commissioner (21 CFR 5.1), Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

SUBCHAPTER A—GENERAL

PART 101—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND THE FAIR PACKAGING AND LABELING ACT

1. By adding new paragraph (c) to § 101.17 to read as follows:

§ 101.17 Food labeling warning statements.

* * * * *

(c) *Self-pressurized containers with a chlorofluorocarbon propellant.* (1) In addition to the warning required by paragraphs (a) and (b) of this section, the label on each package of a food in a self-pressurized container in which the propellant consists in whole or in part of a fully halogenated chlorofluoroalkane (chlorofluorocarbon) shall bear the following warning:

Warning—Contains a chlorofluorocarbon that may harm the public health and environment by reducing ozone in the upper atmosphere.

(2) The warning required by paragraph (c)(1) of this section shall appear on an appropriate panel with such prominence and conspicuousness as to render it likely to be read and understood by ordinary individuals under normal conditions of purchase. The warning may appear on a firmly affixed tag, tape, card, or sticker or similar overlabeling attached to the package. The warning shall comply in all other respects with § 101.2, e.g., type-size requirements.

(3) The warning required by paragraph (c)(1) of this section is applicable only to self-pressurized containers that use chlorofluorocarbons in whole or in part as a propellant to expel from the container liquid or solid material different from the propellant, but the warning is not applicable to the use of chlorofluorocarbon as a stabilizer in food toppings and spreads.

SUBCHAPTER D—DRUGS FOR HUMAN USE

PART 369—INTERPRETATIVE STATEMENTS RE WARNINGS ON DRUGS AND DEVICES FOR OVER-THE-COUNTER SALE

Subpart B—Warning and Caution Statements for Drugs

2. By adding to § 369.21 the following new paragraphs at the end of the listing for Drugs in Dispensers Pressurized by Gaseous Propellants to read as follows:

§ 369.21 Drugs: warning and caution statements required by regulations.

* * * * *

DRUGS IN DISPENSERS PRESSURIZED BY GASEOUS PROPELLANTS

* * * * *

In addition to the above warnings, the label on each package of a drug in a self-pressurized container in which the propellant consists in whole or in part of a fully halogenated chlorofluoroalkane (chlorofluorocarbon) shall bear the following warning:

Warning—Contains a chlorofluorocarbon that may harm the public health and environment by reducing the ozone in the upper atmosphere.

This required warning for self-pressurized containers that contain a fully halogenated chlorofluorocarbon shall appear on an appropriate panel with such prominence and conspicuousness as to render it likely to be read and understood by ordinary individuals under normal conditions of purchase. The warning may appear on a firmly affixed tag, tape, card, or sticker or similar overlabeling attached to the package.

The warning for self-pressurized containers that contain a fully halogenated chlorofluorocarbon is not required and should not be used for metered-dose adrenergic bronchodilators for oral inhalation and contraceptive vaginal foams.

The warning is required only on self-pressurized containers that use a chlorofluorocarbon in whole or in part as a propellant to expel from the container liquid or solid material different from the propellant.

* * * * *

PART 501—ANIMAL FOOD LABELING

Subpart A—General Provisions

3. By adding to § 501.17 new paragraph (c) to read as follows:

§ 501.17 Animal food labeling warning statements.

* * * * *

(c) *Self-pressurized containers with a chlorofluorocarbon propellant.* (1) in addition to the warning required by paragraphs (a) and (b) of this section, the label on each package of a food in a self-pressurized container in which the propellant consists in whole or in part of a fully halogenated chlorofluoroalkane (chlorfluorocarbon) shall bear the following warning:

Warning—Contains a chlorofluorocarbon that may harm the public health and environment by reducing the ozone in the upper atmosphere.

(2) The warning required by paragraph (c)(1) of this section shall appear on an appropriate panel with such prominence and conspicuousness as to render it likely to be read and understood by ordinary individuals under normal conditions of purchase. The warning may appear on a firmly affixed tag, tape, card, or sticker or similar overlabeling attached to the package. The warning shall comply in all other respects with § 501.2, e.g., type-size requirements.

(3) The warning required by paragraph (c)(1) of this section is applicable only to self-pressurized containers that use a chlorofluorocarbon in whole or in part as a propellant to expel from the container liquid or solid material different from the propellant.

PART 505—INTERPRETIVE STATEMENTS RE: WARNINGS ON ANIMAL DRUGS FOR OVER-THE-COUNTER SALE

Subpart B—Required Warning and Caution Statements

4. By adding to § 505.10 the following new listing for Dispensers Pressurized by Gaseous Propellants for Drugs, to read as follows:

§ 505.10 Animal drug warning and caution statements required by regulations.

* * * * *

DISPENSERS PRESSURIZED BY GASEOUS PROPELLANTS FOR DRUGS

The label on each package of a drug in a self-pressurized container in which the propellant consists in whole or in part of a fully halogenated chlorofluoroalkane (chlorofluorocarbon) shall bear the following warning:

Warning—Contains a chlorofluorocarbon that may harm the public health and environment by reducing ozone in the upper atmosphere.

This required warning for self-pressurized containers that contain a fully halogenated chlorofluorocarbon shall appear on an appropriate panel with such prominence and conspicuousness as to render it likely to be read and understood by ordinary individuals under normal conditions of purchase. The warning may appear on a firmly affixed tag, tape, card, or sticker or similar overlabeling attached to the package. The warning shall appear prominently and conspicuously as compared to other words, statements, designs, or devices and in bold type on contrasting background, but in no case may the letters be less than 1/16 inch in height.

The warning is required only on a self-pressurized container that uses a chlorofluorocarbon in whole or in part as a propellant to expel from the container liquid or solid material different from the propellant.

* * * * *

SUBCHAPTER G—COSMETICS

PART 740—COSMETIC PRODUCT WARNING STATEMENTS

Subpart B—Warning Statements

5. By adding to § 740.11 new paragraph (c) to read as follows:

§ 740.11 Cosmetics in self-pressurized containers.

* * * * *

(c)(1) In addition to the warnings required by paragraphs (a)(1) and (b)(1) of this section, the label on each package of a cosmetic in a self-pressurized

container in which the propellant consists in whole or in part of a fully halogenated chlorofluoroalkane (chlorofluorocarbon) shall bear the following warning:

Warning—Contains a chlorofluorocarbon that may harm the public health and environment by reducing ozone in the upper atmosphere.

(2) The warning required by paragraph (c)(1) of this section shall appear on an appropriate panel with such prominence and conspicuousness as to render it likely to be read and understood by ordinary individuals under normal conditions of purchase. The warning may appear on a firmly affixed tag, tape, card, or sticker or similar overlabeling attached to the package. The warning shall comply in all other respects with § 740.2, e.g., type-size requirements.

(3) The warning required by paragraph (c)(1) of this section is applicable only to self-pressurized containers that use a chlorofluorocarbon in whole or in part as a propellant to expel from the container liquid or solid material different from the propellant.

SUBCHAPTER H—MEDICAL DEVICES

PART 801—LABELING

Subpart H—Special Requirements for Specific Devices

5. By adding to Part 801 new § 801.425 to read as follows:

§ 801.425 Nonrestricted devices in self-pressurized containers with chlorofluorocarbon propellants.

(a) The label on each package of a nonrestricted device in a self-pressurized container in which the propellant consists in whole or in part of a fully halogenated chlorofluoroalkane (chlorofluorocarbon) shall bear the following warning:

Warning—Contains a chlorofluorocarbon that may harm the public health and environment by reducing ozone in the upper atmosphere.

(b) The warning required by paragraph (a) of this section shall appear on an appropriate panel with such prominence and conspicuousness as to render it likely to be read and understood by ordinary individuals under normal conditions of purchase. The warning may appear on a firmly affixed tag, tape, card, sticker or similar overlabeling attached to the package. The warning shall appear prominently and conspicuously as compared to other words, statements, designs, or devices and in bold type on contrasting background, but in no case may the letter be less than 1/16 inch in height.

(c) The warning in paragraph (a) of this section is not required and should not be used for products intended for metered-dose adrenergic bronchodilators for oral inhalation, and for cytology fixative uses.

(d) The warning required by paragraph (a) of this section is applicable only to self-pressurized containers that use a chlorofluorocarbon in whole or in part as a propellant to expel from the container liquid or solid material different from the propellant.

Effective date: These regulations shall be effective October 31, 1977 for finished products initially introduced into interstate commerce on or after that date.

(Secs. 201(n), 301, 402, 403, 501, 502, 505, 507, 512, 601, 602, 701(a), 52 Stat. 1041–1043 as amended, 1046–1048 as amended, 1049, 1051–1053 as amended, 1054–1055, 57 Stat. 463 as amended, 82 Stat. 343–351 (21 U.S.C. 321(n), 331, 342, 343, 351, 352, 355, 357, 360b, 361, 362, and 371(a)); sec. 101(2), 83 Stat. 853 (42 U.S.C. 4332).)

Dated: April 25, 1977.

SHERWIN GARDNER,
Acting Commissioner of Food and Drugs.

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